

BEFORE THE
CITIZENS FINANCIAL ACCOUNTABILITY OVERSIGHT COMMITTEE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: 1600 PACIFIC HIGHWAY
BOARD CHAMBERS, ROOM 310
SAN DIEGO, CALIFORNIA

DATE: MONDAY, JULY 7, 2008
1 P.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

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BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

1 SAN DIEGO, CALIFORNIA; MONDAY, JULY 7, 2008

2 1 P.M.

3
4 CHAIRMAN CHIANG: WE WILL CONVENE THE --
5 SINCE IT'S 1:05, WE WILL CONVENE THE MEETING OF THE
6 CITIZENS FINANCIAL ACCOUNTABILITY OVERSIGHT
7 COMMITTEE. LET ME ARTICULATE THAT MEMBERS OF THE
8 PUBLIC ARE INVITED TO PROVIDE TESTIMONY AFTER
9 EACH ITEM. IF YOU DO CHOOSE TO MAKE PUBLIC COMMENT,
10 YOU WILL BE LIMITED TO THREE MINUTES. AND FOR
11 EVERYBODY'S CONVENIENCE SAKE, PLEASE MAKE SURE TO
12 TURN OFF YOUR CELL PHONES.

13 MAY I ASK EVERYBODY TO PLEASE RISE SO THAT
14 WE CAN SAY THE PLEDGE OF ALLEGIANCE.

15 (THE PLEDGE OF ALLEGIANCE.)

16 CHAIRMAN CHIANG: THE NEXT ITEM, WE ARE
17 VERY PLEASED TO WELCOME DR. LOREN LIPSON AS A
18 MEMBER. I HAVE TO ADMINISTER THE OATH OF OFFICE.

19 (THE OATH OF OFFICE WAS THEN
20 ADMINISTERED TO DR. LIPSON.)

21 CHAIRMAN CHIANG: THE NEXT ITEM, WE WILL
22 CALL TO ORDER AND DO THE ROLL CALL.

23 MEMBERS DANIEL BRUNNER.

24 MEMBER BRUNNER: HERE.

25 CHAIRMAN CHIANG: DR. LOREN LIPSON.

BARRISTERS' REPORTING SERVICE

1 MEMBER LIPSON: HERE.

2 CHAIRMAN CHIANG: JIM LOTT. JIM WILL BE
3 ATTENDING, BUT HE'S NOT HERE.

4 MRYTLE POTTER.

5 MEMBER POTTER: HERE.

6 CHAIRMAN CHIANG: DR. GURBINDER SADANA.

7 MEMBER SADANA: HERE.

8 CHAIRMAN CHIANG: WE HAVE A QUORUM
9 PRESENT.

10 NEXT ITEM. I WOULD LIKE TO THANK
11 EVERYBODY FOR ATTENDING THIS AFTERNOON AND ASK THAT
12 THEY JOIN ME IN WELCOMING DR. LIPSON TO THIS
13 COMMITTEE. HIS EXPERIENCE AT SOME OF OUR NATION'S
14 MOST PRESTIGIOUS MEDICAL SCHOOLS, AS WELL AS HIS
15 EXPERTISE IN THE AREAS OF GERIATRIC MEDICINE AND
16 LONG-TERM CARE, WILL BE A USEFUL ADDITION TO THIS
17 OVERSIGHT GROUP.

18 PROPOSITION 71, THE STEM CELL RESEARCH AND
19 CURES INITIATIVE, OFFERED CALIFORNIA A UNIQUE AND
20 DIRECT PATH TO ADVANCING MEDICAL RESEARCH, A CALL
21 FOR NEW IDEAS AND NEW COURSES OF ACTION, A CALL FOR
22 PUBLIC SUPPORT AND PRIVATE DEVELOPMENT. IN 2004 THE
23 VOTERS OF THIS STATE SIGNED THEMSELVES UP TO COVER
24 THE TAB BECAUSE THEY BELIEVE THIS RESEARCH WAS THE
25 MOST PROMISING HOPE FOR DISCOVERING CURES TO CHRONIC

BARRISTERS' REPORTING SERVICE

1 AND LIFE-THREATENING DISEASES AND CONDITIONS.

2 THE LAW REQUIRED THAT THE MECHANICS OF
3 THIS PROGRAM ALSO BE PUT UNDER THE MICROSCOPE
4 BECAUSE CALIFORNIA TAX DOLLARS AND OUR TRUST IN
5 PUBLIC WORKS PROJECTS ARE ALL AT STAKE IN THIS
6 IMPORTANT VENTURE. THE CITIZENS FINANCIAL
7 ACCOUNTABILITY OVERSIGHT COMMITTEE WAS CREATED TO
8 FULFILL THAT ROLE.

9 LAST YEAR, AS NEW CHAIR, I EXPLAINED THAT
10 I WANTED US TO TAKE A LOOK AT THE MOST CURRENT
11 REPORTS AND FINANCIAL STATEMENTS. THAT IS WHY WE
12 ARE HERE TODAY, TO MAKE SURE THAT THIS COMMITTEE
13 TAKES AN ACTIVE ROLE IN MAINTAINING THE FINANCIAL
14 INTEGRITY OF THIS PROGRAM.

15 HINDSIGHT IS NOT OVERSIGHT, AND WE MUST
16 NOT ONLY FOCUS ON HOW PUBLIC DOLLARS ARE SPENT, BUT
17 ALSO PLANS TO SPEND THEM IN THE FUTURE. LAST
18 NOVEMBER WE SET THIS PANEL'S COURSE AND ALSO MADE
19 CLEAR THAT WHILE WE EXPECT CIRM TO OPERATE IN A
20 TRANSPARENT MANNER, WE MUST MAINTAIN THE SAME
21 STANDARDS OURSELVES. NOT EVERY MEMBER OF THE PANEL
22 IS REQUIRED TO DISCLOSE THEIR FINANCIAL INTEREST IN
23 ORDER TO REMOVE ANY APPEARANCE OF CONFLICT IN OUR
24 COMMITTEE'S ACTIONS.

25 TODAY WE ARE REVIEWING SEVERAL AUDITS,

BARRISTERS' REPORTING SERVICE

1 INCLUDING ONE PERFORMED BY MY OFFICE, THAT LOOK AT
2 PAST PERFORMANCE OF CIRM. WE'RE ALSO GOING TO HEAR
3 ABOUT LEGISLATION THAT CAN IMPROVE ITS GOVERNANCE
4 STRUCTURE SO THAT WE CAN PURSUE THIS REVOLUTIONARY
5 FIELD OF SCIENCE WHILE ALSO PROTECTING THE PUBLIC'S
6 INVESTMENT AND ITS CONFIDENCE IN THIS PROGRAM.

7 THE NEXT ITEM IS THE TRANSCRIPT OF THE
8 NOVEMBER 27, 2007, CFAOC ITEM. THIS IS AN
9 INFORMATION ITEM, SO WE'RE NOT GOING TO VOTE ON IT,
10 BUT I JUST WANTED TO MAKE SURE IT'S COVERED. AND WE
11 WILL BRING IT UP NEXT HEARING AS AN ACTION ITEM.
12 BUT DOES ANYBODY WISH TO MAKE ANY COMMENTS?

13 THEN WE'LL GO TO THE NEXT ITEM, THE
14 MACIAS, GINI & O'CONNELL PRESENTS THE 2006-2007
15 INDEPENDENT FINANCIAL AUDIT. YOU ALSO HAVE CIRM'S
16 AUDIT RESPONSE AND THE STATE'S CONTROLLER'S OFFICE
17 AUDIT REVIEW REPORT.

18 COULD I HAVE A REPRESENTATIVE?

19 MR. NEEQUAYE: GOOD AFTERNOON. MY NAME IS
20 ANTHONY NEEQUAYE. I'M AUDIT DIRECTOR WITH MACIAS,
21 GINI & O'CONNELL, AND I'M HERE TO GO BRIEFLY OVER
22 THE FINANCIAL STATEMENTS AND THE REQUIRED AUDITOR
23 COMMUNICATIONS FOR THE CALIFORNIA INSTITUTE OF
24 REGENERATIVE MEDICINE.

25 CHAIRMAN CHIANG: THANK YOU.

BARRISTERS' REPORTING SERVICE

1 MR. NEEQUAYE: YOU SHOULD HAVE A COPY OF
2 THE CERTIFIED FINANCIAL STATEMENTS IN YOUR PACKAGE.
3 AND THE FIRST THING I WOULD LIKE TO DRAW YOUR
4 ATTENTION TO IS PAGES 1 AND 2, WHICH ARE THE
5 INDEPENDENT AUDITOR'S REPORTS.

6 ON PAGE 1 IN THE FIRST PARAGRAPH, WE
7 SPECIFICALLY DELINEATE RESPONSIBILITIES. WE
8 INDICATE THAT THESE FINANCIAL STATEMENTS ARE THE
9 RESPONSIBILITY OF CIRM'S MANAGEMENT. OUR
10 RESPONSIBILITY IS TO EXPRESS OPINIONS ON THESE
11 FINANCIAL STATEMENTS BASED ON OUR AUDIT. SO THESE
12 ARE YOUR STATEMENTS. ALL WE HAVE DONE IS PERFORM A
13 SERVICE, WHICH BASICALLY IS TO EXPRESS AN OPINION ON
14 THESE NUMBERS.

15 IN THE SECOND PARAGRAPH WE GO INTO A
16 LITTLE BIT OF DETAIL AS TO THE REGULATIONS AND
17 BYLAWS UNDER WHICH WE PERFORM THIS ENGAGEMENT. AND
18 WE USE STANDARDS APPLICABLE TO GOVERNMENT AUDITING
19 STANDARDS, AND WE ALSO TOOK A LOOK AT YOUR INTERNAL
20 CONTROL IN THE PERFORMANCE OF THESE AUDITS. WE FEEL
21 THAT THIS IS IMPORTANT TO LET YOU KNOW.

22 IN THE THIRD PARAGRAPH IS WHERE WE
23 SUMMARIZE THE RESULTS OF OUR AUDITS. IN THE THIRD
24 PARAGRAPH WE SAY IN OUR OPINION THE FINANCIAL
25 STATEMENTS REFERRED TO ABOVE PRESENT FAIRLY IN ALL

BARRISTERS' REPORTING SERVICE

1 MATERIAL RESPECTS THE RESPECTIVE FINANCIAL POSITION
2 OF THE GOVERNMENTAL ACTIVITIES AND THE MAJOR FUND OF
3 CIRM AS OF JUNE 30, 2007.

4 IN THE COLLOQUIAL EXPRESSION, THIS IS
5 KNOWN AS A CLEAN OPINION. SO THIS BASICALLY CONVEYS
6 THE RESULTS OF OUR AUDITS.

7 THE FOURTH PARAGRAPH ON PAGE 1 BASICALLY
8 JUST LAYS OUT THAT, ONCE AGAIN, THIS AUDIT WAS
9 PERFORMED IN ACCORDANCE WITH GOVERNMENT AUDITING
10 STANDARDS; I. E. , WE EXERCISE OR PERFORM ADDITIONAL
11 PROCEDURES AS REQUIRED FOR GOVERNMENT ENTITIES. AND
12 THERE'S A REPORT WHICH IS BEHIND THIS REPORT WHICH
13 GIVES US THE RESULTS OF PERFORMING THIS AUDIT IN
14 ACCORDANCE WITH GOVERNMENT AUDITING STANDARDS.

15 THAT IS A BRIEF SUMMARY OF THE RESULTS OF
16 OUR AUDIT. AND IF THERE ARE NO FURTHER QUESTIONS,
17 I'D LIKE TO GO ON TO AUDITOR COMMUNICATIONS WHICH
18 ARE REQUIRED. BASICALLY OUR PROFESSION REQUIRES
19 THAT WE ADDRESS THE GOVERNING BODY OR THE AUDIT
20 COMMITTEE. WE ADDRESS THEM WITH REQUIRED
21 COMMUNICATIONS. WE ARE REQUIRED TO TELL YOU ABOUT
22 THE CONDUCT OF THE AUDITS BECAUSE WE HAVE GONE OUT
23 AND PERFORMED THIS SERVICE, WE'VE GIVEN YOU A CLEAN
24 OPINION; BUT IF THERE ARE ANY PROBLEMS DURING THE
25 PERFORMANCE OF THE AUDIT, THIS IS THE APPROPRIATE

BARRISTERS' REPORTING SERVICE

1 FORUM FOR ME TO AT LEAST LET YOU KNOW IF THERE WERE
2 ANY PROBLEMS OR THERE WERE ANY DIFFICULTIES
3 ENCOUNTERED IN PERFORMING THIS AUDIT.

4 YOU SHOULD HAVE A COPY OF THIS REPORT,
5 WHICH IS OUR 61 REPORT, ALSO IN YOUR PACKAGE. WELL,
6 WE CALL IT THE REPORT TO MANAGEMENT.

7 SO IF WE SKIP TO THE HEART OF THIS REPORT,
8 WHICH IS ON PAGE 2, THERE ARE CERTAIN REQUIRED
9 COMMUNICATIONS WHICH WE AS AUDITORS HAVE TO RENDER
10 TO, AS I MENTIONED BEFORE, THE GOVERNING BODY. SOME
11 OF THESE REQUIRED COMMUNICATIONS ARE, AND I'M GOING
12 TO HIGHLIGHT A FEW IMPORTANT ONES, FIRST OFF, POINT
13 I, WHICH IS THE FIRST POINT, OUR RESPONSIBILITY
14 UNDER GENERALLY ACCEPTED AUDITING STANDARDS AND
15 GOVERNMENT AUDITING STANDARDS. WE BASICALLY LAY OUT
16 TO YOU OVER HERE THAT WE ARE GOING TO PERFORM THE
17 AUDIT IN ACCORDANCE WITH THESE STANDARDS.

18 II, WHICH IS SIGNIFICANT ACCOUNTING
19 POLICIES AND UNUSUAL TRANSACTIONS. IF THERE WAS
20 SOMETHING UNUSUAL OVER HERE, WE WOULD LET YOU KNOW
21 IN THIS PARAGRAPH. AND OVER HERE UNDER THIS BULLET
22 POINT, WE SAY THERE WERE NO NEW ACCOUNTING POLICIES
23 ADOPTED; I.E., THERE WAS NOTHING UNUSUAL DURING THE
24 CURRENT YEAR.

25 NOW LET ME SKIP TO POINT IV, WHICH IS

BARRISTERS' REPORTING SERVICE

1 POINT 4, AUDIT ADJUSTMENTS. AND OVER HERE WE SAY
2 THAT THERE WERE NO SIGNIFICANT AUDIT ADJUSTMENTS.
3 AUDIT ADJUSTMENTS ARISE WHEN WE PERFORM OUR TEST
4 WORK, AND WE FIND OUT THAT THERE ARE SIGNIFICANT
5 ERRORS, AND WE PROPOSE CORRECTING JOURNAL ENTRIES.
6 SO IN THIS POINT OVER HERE, WE SAY NONE OF THE
7 ADJUSTMENTS THAT WE POST WERE SIGNIFICANT EITHER
8 INDIVIDUALLY OR IN THE AGGREGATE.

9 POINT V, WHICH IS ROMAN NUMERAL V, WHICH
10 IS 5, DISAGREEMENTS WITH MANAGEMENT. WE ALSO WANT
11 TO POINT OUT OVER HERE THAT WE DID NOT HAVE ANY
12 SIGNIFICANT DISAGREEMENT WITH MANAGEMENT.

13 AND LET ME JUST JUMP TO POINT VIII, WHICH
14 IS ROMAN NUMERAL VIII, DIFFICULTIES IN PERFORMING
15 THE AUDIT. AND WE DID NOT ENCOUNTER ANY SIGNIFICANT
16 DIFFICULTIES IN PERFORMING THE AUDIT.

17 NOW, WITHIN THIS PACKET WE ALSO HAVE
18 MANAGEMENT COMMENTS OR SUGGESTIONS WHICH WE PROVIDE
19 TO YOU AS PART OF OUR SERVICE FOR IMPROVING INTERNAL
20 CONTROLS. AT YOUR LEISURE, YOU CAN READ THEM. IF
21 YOU HAVE ANY QUESTIONS, I WOULD BE MORE THAN HAPPY
22 TO ANSWER THEM.

23 CHAIRMAN CHIANG: THANK YOU.

24 MR. NEEQUAYE: THANK YOU.

25 CHAIRMAN CHIANG: QUESTIONS OR COMMENTS?

BARRISTERS' REPORTING SERVICE

1 WOULD THE CIRM STAFF LIKE TO RESPOND? NO. NO.
2 OKAY.

3 THEN MAY I HAVE CAROLYN BAEZ FROM MY
4 OFFICE PRESENT THE REVIEW?

5 MS. BAEZ: GOOD AFTERNOON. CAROLYN BAEZ,
6 AND I'M AN AUDIT MANAGER WITH THE STATE CONTROLLER'S
7 OFFICE FINANCIAL AUDITS BUREAU. AND OUR BUREAU WAS
8 RESPONSIBLE FOR PERFORMING THE QUALITY CONTROL
9 REVIEW OF MACIAS, GINI & O'CONNELL'S WORKING PAPERS
10 FOR THEIR FINANCIAL AUDIT OF CIRM FOR 2006-2007.
11 AND THE SCO IS REQUIRED BY THE HEALTH AND SAFETY
12 CODE SECTION 125290.30 TO REVIEW THE ANNUAL
13 FINANCIAL AUDIT AND TO ISSUE A PUBLIC REPORT OF THAT
14 REVIEW.

15 THE OBJECTIVES OF OUR QUALITY CONTROL
16 REVIEW WERE TO DETERMINE WHETHER THE AUDIT WAS
17 CONDUCTED IN ACCORDANCE WITH GENERALLY ACCEPTED
18 AUDITING STANDARDS, GOVERNMENT AUDITING STANDARDS,
19 AND CALIFORNIA BUSINESS AND PROFESSIONS CODE.

20 AND WE CONCLUDED THAT THE AUDIT WAS
21 PERFORMED IN ACCORDANCE WITH THOSE STANDARDS AND
22 REQUIREMENTS, AND NO EXCEPTIONS WERE IDENTIFIED.

23 IF YOU HAVE ANY QUESTIONS REGARDING THE
24 REVIEW, I'D BE HAPPY TO ANSWER THEM.

25 CHAIRMAN CHIANG: VERY GOOD. I UNDERSTAND

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1 THE MANAGEMENT LETTER RECOMMENDED A FORMAL POLICY
2 FOR MONITORING AND REVIEWING. DO YOU HAVE ANY -- DO
3 YOU HAVE ANY THOUGHTS ABOUT WHAT FORMAL POLICY WE
4 SHOULD HAVE IN PLACE FOR A DONOR CONTRIBUTION
5 AGREEMENT? THERE'S BEEN PUBLIC DISCUSSION ABOUT
6 THAT. I JUST WANTED TO HAVE A SENSE EVEN THOUGH
7 IT'S NOT COVERED FORMALLY.

8 MR. BAEZ: RIGHT. WELL, AS PART OF OUR
9 REVIEW WE JUST REVIEWED, THEIR DOCUMENTATION OF WHAT
10 THEY DID WAS ADEQUATE AND IF THEY FOLLOWED THE
11 STANDARDS. WE DIDN'T REALLY EXAMINE ANY
12 RECOMMENDATIONS THEY MADE OTHER THAN TO SEE IF THEY
13 WERE SUPPORTED. WE DIDN'T LOOK AT THE ACTUAL IF
14 THEY WERE -- WOULD BE -- WHAT THEY SHOULD ACTUALLY
15 DO. WE JUST LOOKED TO SEE IF ANY RECOMMENDATIONS
16 WERE SUPPORTED BY THE AUDIT WORK AND ANY CRITERIA.

17 CHAIRMAN CHIANG: DO YOU HAVE THE -- I
18 KNOW THIS IS A UNIQUE BODY. DO YOU HAVE A SENSE OF
19 ANYTHING SIMILAR TAKING PLACE ELSEWHERE?

20 MS. BAEZ: NOT THAT I'M FAMILIAR WITH, NO.

21 CHAIRMAN CHIANG: WOULD ANYBODY FROM CIRM
22 LIKE TO MAKE A COMMENTARY?

23 MS. BAEZ: THANK YOU.

24 CHAIRMAN CHIANG: THANK YOU. BOB, PLEASE
25 INTRODUCE YOURSELF.

BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: ROBERT KLEIN, CHAIRMAN OF THE
2 GOVERNING BOARD OF THE CALIFORNIA INSTITUTE OF
3 REGENERATIVE MEDICINE. IT'S A PRIVILEGE TO ADDRESS
4 YOU TODAY.

5 AS TO SPECIFIC DONATIONS, WE HAVE ADOPTED
6 STANDARDS THAT REQUIRE DISCLOSURE IF THEY'RE OVER A
7 SPECIFIC DOLLAR AMOUNT. WE ALSO HAVE STANDARDS THAT
8 MAKE SURE THERE'S NO CONFLICTS IN THE DONATION. WE
9 ALSO HAVE A PROCESS, BEFORE THE DONATION IS BROUGHT
10 TO THE BOARD, TO REVIEW ADMINISTRATIVELY THE
11 BACKGROUND OF THE DONOR, MAKING SURE THAT THE DONOR
12 IS OF THE HIGHEST QUALITY AS AN INDIVIDUAL AS
13 INDICATED BY PERSONAL CHARACTER.

14 AND WE HAVE A RECORD AT THIS POINT OF
15 BEING VERY SUCCESSFUL IN THE ADMINISTRATION OF
16 DONATIONS. AT THE TIME THAT THIS AGENCY WAS IN
17 COURT, IT WAS CRITICAL THAT WE RECEIVE A DONATION TO
18 ALLOW WORKING CAPITAL TO FUND THE AGENCY BECAUSE THE
19 OPPOSITION'S VIEWPOINT WAS THAT THEY COULD BANKRUPT
20 THE AGENCY BY HAVING LEGAL COST AND KEEPING US FROM
21 ISSUING ANY BONDS SO THAT WE WOULD NOT HAVE THE
22 FUNDS TO OPERATE.

23 THE DOLBY FAMILY, FAMOUS FOR DOLBY SOUND,
24 COMPLETELY OBVIOUSLY UNRELATED TO STEM CELL
25 RESEARCH, CONTRIBUTED \$5 MILLION TO THE AGENCY AT

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1 THAT TIME TO ALLOW US TO CONTINUE TO OPERATE. AND
2 DONATIONS NOT ONLY HAVE BEEN AN IMPORTANT PART OF
3 WHAT WE HAVE ACCOMPLISHED, BUT THE DONATIONS HAVE
4 VERY SPECIFICALLY BEEN PROVIDED FOR IN THE
5 INITIATIVE. SO IT WAS CONTEMPLATED IN THE
6 INITIATIVE AND SPECIFICALLY AUTHORIZED IN THE
7 INITIATIVE. AND WE'RE TRYING TO PURSUE THAT
8 OPPORTUNITY TO LEVERAGE THE STATE TAXPAYERS' FUNDS
9 IN ADVANCING MEDICAL RESEARCH. THANK YOU.

10 CHAIRMAN CHIANG: BOB, CAN YOU SHARE YOUR
11 EXPERIENCES ACROSS THE STATE AS TO WHAT THE
12 PRACTICES ARE WITH OTHER ENTITIES INVOLVED IN THIS
13 AREA?

14 MR. KLEIN: WELL, THE UNIVERSITY OF
15 CALIFORNIA SYSTEM, WHICH, OF COURSE, IS INVOLVED IN
16 SIMILAR KINDS OF MEDICAL RESEARCH, HAS GONE TO THE
17 POINT OF EVEN FORMALIZING FOUNDATIONS THAT BECOME
18 COMPANIONS TO THE UC SYSTEM. SO THE UC SYSTEM
19 RECEIVES DONATIONS VERY DIRECTLY.

20 FOR EXAMPLE, UC IRVINE'S STEM CELL CENTER
21 IS BEING FUNDED IN PART BY A \$15 MILLION DONATION BY
22 THE GROSS FAMILY. ELI BROAD HAS CONTRIBUTED 25
23 MILLION TO UCLA FOR THEIR STEM CELL CENTER. SO THE
24 UC SYSTEM HAS A VERY SYSTEMATIC WAY OF FOLLOWING THE
25 SAME KIND OF PROCEDURES WE ARE IN VETTING THOSE, BUT

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1 WHEN THEY DETERMINE THERE IS NO CONFLICT, OF
2 ACCEPTING THOSE AND HELPING LEVERAGE TAXPAYER FUNDS
3 TO ADVANCE MEDICAL RESEARCH VERY SPECIFICALLY.

4 CHAIRMAN CHIANG: VERY GOOD. THANK YOU.
5 ARE THERE ANY PUBLIC COMMENTS?

6 MR. SIMPSON: JOHN SIMPSON FROM THE
7 ORGANIZATION NOW KNOWN AS CONSUMER WATCHDOG,
8 FORMERLY THE FOUNDATION FOR TAXPAYER AND CONSUMER
9 RIGHTS. I AM DIRECTOR OF OUR STEM CELL OVERSIGHT
10 ACCOUNTABILITY PROJECT.

11 I JUST WONDERED. I WAS -- I'M GLAD TO BE
12 ABLE TO ADDRESS YOU TODAY, MR. CHAIRMAN AND MEMBERS
13 OF THE COMMITTEE. WOULD IT BE APPROPRIATE TO JUST
14 PUT A QUESTION TO MR. KLEIN? WHICH IS DOES CIRM
15 ENVISION GOING FURTHER AND ACTUALLY FORMING A
16 FOUNDATION?

17 CHAIRMAN CHIANG: JOHN, YOU CAN'T ASK THAT
18 QUESTION TO THEM. YOU CAN ASK IT TO ME, AND I'LL
19 ASK HIM THE QUESTION.

20 MR. SIMPSON: MR. CHAIRMAN, COULD YOU
21 KINDLY ASK WHETHER CIRM IS CONTEMPLATING ACTUALLY
22 GOING AS FAR AS FORMING A FOUNDATION TO TAKE IN
23 DONATIONS?

24 CHAIRMAN CHIANG: MR. KLEIN, IF YOU'D
25 PLEASE RESPOND TO WHETHER CIRM IS CONTEMPLATING

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1 STARTING A FOUNDATION TO TAKE IN THOSE KINDS OF
2 DONATIONS.

3 MR. KLEIN: YES, MR. CHAIRMAN. THE
4 CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE IS
5 STUDYING ALL OF THE UC FOUNDATIONS TO SEE IF THIS IS
6 A MODEL WHERE WE COULD FURTHER LEVERAGE STATE
7 TAXPAYER MONEY. IF YOU WILL NOTE FROM A LATER
8 PRESENTATION, IN THE MAJOR FACILITIES GRANTS
9 PROGRAM, BASED ON ONE OF THE PUBLIC CRITERIA THAT I
10 THINK MR. SIMPSON LAUDED AS AN EXAMPLE AND A MODEL
11 FOR STATE AGENCIES IN CALIFORNIA, WE HAD LEVERAGED
12 BY THE GRANTEE INSTITUTIONS AS A CRITERIA. SO OUR
13 \$270 MILLION IN STATE GRANT FUNDS FOR MAJOR
14 FACILITIES WAS MATCHED BY \$880 MILLION IN DONOR
15 FUNDS TO INSTITUTIONS. ABOUT 60 PERCENT ARE UC
16 SYSTEM INSTITUTIONS AND INSTITUTIONAL COMMITMENTS
17 FROM THOSE INSTITUTIONS.

18 SO WE HAVE SEEN THAT THERE'S A TREMENDOUS
19 CIVIC OUTPOURING FROM THE DONOR SOCIETY AND
20 NONPROFIT ORGANIZATIONS IN SUPPORTING OUR MISSION.
21 AND SO WE ARE INVESTIGATING THE BEST PRACTICE MODELS
22 OF THE UC SYSTEM TO SEE IF THAT'S SOMETHING THAT WE
23 SHOULD PROCEED ON.

24 CHAIRMAN CHIANG: THANK YOU. ANY OTHER
25 FURTHER PUBLIC COMMENT? OKAY.

BARRISTERS' REPORTING SERVICE

1 NEXT ITEM IS ITEM NO. 7, THE 2006-2007
2 STATE CONTROLLER'S OFFICE REVIEW OF CONFLICT OF
3 INTEREST POLICIES, GRANT ADMINISTRATION,
4 ADMINISTRATIVE EXPENSES, AND EXPENDITURES.

5 LAST NOVEMBER I DIRECTED MY OFFICE TO
6 CONDUCT A REVIEW OF CIRM TO DETERMINE WHETHER CIRM
7 COMPLIED WITH THE REQUIREMENTS OF PROPOSITION 71 AS
8 IT RELATES TO CIRM'S CONFLICT OF INTEREST POLICIES,
9 GRANT ADMINISTRATION, AND ADMINISTRATIVE EXPENSES,
10 AND EXPENDITURES.

11 THIS AUDIT WAS RELEASED MAY 12TH, AND I AM
12 HAPPY TO HAVE SUZANNE GOODWIN-STENBERG PRESENT THE
13 AUDIT TO THE COMMITTEE. WELCOME.

14 MS. GOODWIN-STENBERG: GOOD AFTERNOON,
15 CONTROLLER CHIANG AND COMMITTEE MEMBERS. MY NAME IS
16 SUZANNE GOODWIN-STENBERG, AND I'M AN AUDIT MANAGER
17 IN THE FINANCIAL AUDIT BUREAU AT STATE CONTROLLER'S
18 OFFICE.

19 AND, AS YOU SAID, THE CONTROLLER'S OFFICE
20 ISSUED OUR REVIEW REPORT ON MAY 1ST, AND THIS WAS
21 BASED ON OUR REVIEW OF CIRM'S CONFLICT OF INTEREST
22 POLICIES, GRANT ADMINISTRATION, AND ADMINISTRATIVE
23 EXPENDITURES, AND EXPENSES. WE DID OUR REVIEW UPON
24 THE CONTROLLER'S REQUEST. AND OUR REVIEW
25 ENCOMPASSED THE PERIOD FROM JULY 1, 2006, THROUGH

BARRISTERS' REPORTING SERVICE

1 DECEMBER 31, 2007.

2 WE LIMITED OUR SCOPE TO PLANNING AND
3 PERFORMING REVIEW PROCEDURES TO OBTAIN REASONABLE
4 ASSURANCE THAT CIRM COMPLIED WITH THE REQUIREMENTS
5 OF PROPOSITION 71 RELATIVE TO THE CONFLICT OF
6 INTEREST POLICIES, GRANT ADMINISTRATION, AND
7 ADMINISTRATIVE EXPENSES, AND EXPENDITURES.

8 WE DID NOT REVIEW EXPENDITURES FROM JULY
9 1, 2006, THROUGH JULY 30, 2007, AS THESE WERE
10 REVIEWED BY THE INDEPENDENT AUDITOR IN CIRM'S
11 FINANCIAL AUDIT.

12 OUR REVIEW OBJECTIVES WERE TO DETERMINE
13 THE ADEQUACY OF CIRM'S POLICIES AND PROCEDURES FOR
14 GRANTS ADMINISTRATION, TO DETERMINE THEIR COMPLIANCE
15 WITH THE CONFLICT OF INTEREST RULES AND BEST
16 PRACTICES, TO DETERMINE COMPLIANCE WITH PROPOSITION
17 71 REQUIREMENTS RELATED TO GRANTS ADMINISTRATION,
18 DETERMINE THE ADEQUACY OF THE MANDATED GRANTEE
19 REPORTING REQUIREMENTS, AND, FINALLY, TO DETERMINE
20 WHETHER CIRM'S ADMINISTRATIVE EXPENSES ARE IN LINE
21 WITH PROPOSITION 71 REQUIREMENTS AND IF THEY WERE
22 PROPERLY APPROVED AND AUTHORIZED.

23 DURING OUR REVIEW WE REVIEWED
24 APPROXIMATELY 31 PERCENT OF ALL GRANTS AWARDED AND
25 APPROXIMATELY 62 PERCENT OF ALL EXPENDITURES DURING

BARRISTERS' REPORTING SERVICE

1 OUR REVIEW SCOPE. EXCEPT FOR THE ISSUE CONCERNING
2 SPECIALISTS FAILING TO SIGN POSTREVIEW CONFLICT OF
3 INTEREST CERTIFICATION FORMS, WE FOUND THAT CIRM'S
4 CONFLICT OF INTEREST POLICIES AND PROCEDURES ARE
5 ADEQUATE AND THAT THEY WERE PROPERLY FOLLOWED.

6 AS NOTED IN OUR REVIEW REPORT, WE HAVE ONE
7 FINDING THAT, ALTHOUGH THE SPECIALISTS WORKING WITH
8 THE GRANTS WORKING GROUP DID SIGN THEIR PREREVIEW
9 CONFLICT OF INTEREST STATEMENTS AND CONFIDENTIAL
10 FINANCIAL DISCLOSURE FORMS, THEY DID NOT SIGN
11 POSTREVIEW CERTIFICATION FORMS REGARDING CONFLICT OF
12 INTEREST, CONFIDENTIALITY, AND NONDISCLOSURE OF
13 INFORMATION AS REQUIRED.

14 WHEN WE SPOKE WITH CIRM, THEY INFORMED US
15 THAT THE SPECIALISTS PARTICIPATE IN THE MEETINGS VIA
16 TELECONFERENCE, AND THAT'S WHY THEY DID NOT SIGN THE
17 POSTREVIEW FORMS. WE RECOMMENDED THAT THE
18 SPECIALISTS ALSO SIGN THE POSTREVIEW CERTIFICATION
19 FORM REGARDING CONFLICT OF INTEREST,
20 CONFIDENTIALITY, AND NONDISCLOSURE FOR EACH MEETING
21 IN WHICH THEY DO PARTICIPATE EVEN IF IT IS VIA
22 TELECONFERENCE. CIRM AGREED AND IN THEIR RESPONSE
23 TOLD US THAT THEY IMPLEMENTED THIS NEW POLICY
24 BEGINNING WITH THEIR APRIL 9TH THROUGH 11TH GRANTS
25 WORKING GROUP MEETING.

BARRISTERS' REPORTING SERVICE

1 ON ONE OTHER NOTE, THROUGH INTERAGENCY
2 AGREEMENTS, THE CONTROLLER'S OFFICE HAS PROVIDED
3 NONAUDIT SERVICES TO CIRM SINCE ITS INCEPTION.
4 THESE SERVICES INCLUDE THE CONTROLLER'S DEPARTMENTAL
5 ACCOUNTING AND HUMAN RESOURCES OFFICES PROVIDE
6 ACCOUNTING AND PAYROLL SERVICES TO CIRM. IN
7 ADDITION, BEGINNING JANUARY 1, 2008, THE
8 CONTROLLER'S DEPARTMENTAL ACCOUNTING OFFICER WAS
9 APPOINTED AS CIRM'S CHIEF FINANCIAL OFFICER. AS THE
10 APPOINTMENT WAS MADE OUTSIDE OF THE TIME PERIOD OF
11 THE SCOPE OF OUR AUDIT, WE FEEL THIS DID NOT IMPAIR
12 OUR INDEPENDENCE.

13 IN ADDITION, WITH OUR REPORTING STRUCTURE
14 WITHIN THE CONTROLLER'S OFFICE, WE REPORT -- THE
15 DIVISION OF AUDITS REPORTS SEPARATELY THAN THE
16 DIVISION OF ACCOUNTING REPORTING DOES THROUGH A
17 DIFFERENT CHANNEL TO THE CONTROLLER. HOWEVER, IN
18 ACCORDANCE WITH GENERALLY ACCEPTED GOVERNMENTAL
19 AUDITING STANDARDS, WE DID NEED TO DISCLOSE THIS.

20 AND IF YOU HAVE ANY QUESTIONS, GLAD TO
21 ANSWER THEM.

22 CHAIRMAN CHIANG: THANK YOU, SUZANNE, FOR
23 THAT REVIEW. ARE THERE ANY QUESTIONS? I'M PLEASED
24 TO SEE THAT THE AUDIT SHOWS THAT THE INSTITUTE'S
25 PRACTICES ARE IN COMPLIANCE WITH PROPOSITION 71.

BARRISTERS' REPORTING SERVICE

1 ARE THERE ANY PUBLIC COMMENTS?

2 MR. SIMPSON: JOHN SIMPSON WITH CONSUMER
3 WATCHDOG. WE WERE NOT AT ALL SURPRISED THAT THE
4 AUDIT FOUND THAT THE PROCEDURES WERE IN COMPLIANCE
5 WITH PROPOSITION 71. WE WOULD SUGGEST THAT THE CRUX
6 OF THE PROBLEM IS THAT PROP 71, IN FACT, BUILDS IN
7 CONFLICTS OF INTEREST THAT REALLY ARE INADEQUATELY
8 ADDRESSED BY THE VERY STRUCTURE OF THE BOARD ITSELF.
9 WE'VE BEEN ON RECORD AS POINTING THAT OUT IN A
10 NUMBER OF FORUMS. I JUST WANTED TO MAKE THAT POINT
11 HERE.

12 SO THIS DID NOT ESSENTIALLY SAY THERE ARE
13 NO CONFLICTS OF INTEREST. IT ESSENTIALLY SAID THE
14 RULES, AS THEY ARE WRITTEN, ARE BEING FOLLOWED. AND
15 WE WOULD SUGGEST THAT THOSE RULES ARE INADEQUATE.
16 THANK YOU.

17 CHAIRMAN CHIANG: THANK YOU. GOOD
18 AFTERNOON.

19 MR. REED: GOOD AFTERNOON. I'M DON REED,
20 CALIFORNIANS FOR CURES. MY SON, ROMAN REED, WAS THE
21 INSPIRATION FOR THE ROMAN REED SPINAL CORD INJURY
22 RESEARCH ACT, AND I FOLLOW THIS WITH GREAT INTEREST.
23 THANK YOU FOR YOUR EFFORTS.

24 THE ICOC IS, TO MY MIND, A MODEL OF
25 EXPERTISE. IT IS NOT A CONFLICT OF INTEREST WAITING

BARRISTERS' REPORTING SERVICE

1 TO HAPPEN AS SOME WOULD IMPLY, BUT IT IS A
2 CONVENTION, A COMMITTEE OF EXPERTS. AND I THINK
3 THIS IS NOT JUST MY OPINION. THIS IS THE OPINION OF
4 THE COURT SYSTEM OF CALIFORNIA.

5 I'D LIKE TO READ ONE PARAGRAPH FROM THE
6 APPEALS COURT FINDING. "BY APPROVING PROPOSITION
7 71, THE VOTERS HAVE DETERMINED THAT THE ADVANTAGES
8 OF PERMITTING PARTICULARLY KNOWLEDGEABLE PERSONS TO
9 DECIDE WHICH RESEARCH PROJECTS TO FUND OUTWEIGHS ANY
10 CONCERNS THAT THESE DECISIONS MAY BE INFLUENCED BY
11 THE PERSONAL OR PROFESSIONAL INTERESTS OF THOSE
12 MEMBERS SO LONG AS THOSE MEMBERS DO NOT PARTICIPATE
13 IN ANY DECISIONS TO AWARD GRANTS THEMSELVES OR THEIR
14 EMPLOYERS. "

15 I TRY TO GO TO ALL THE MEETINGS I POSSIBLY
16 CAN, AND IT'S ALMOST FUNNY SOMETIMES TO SEE THE
17 DEGREE THAT ICOC MEMBERS WILL GO TO TO SAY, "WELL,
18 CAN I COMMENT ON THAT? NO, I CAN'T. I'M SORRY. I
19 WON'T SAY ANYTHING." THEY WORK REALLY HARD TO
20 FOLLOW EVERY LETTER OF THE LAW, AND THE SPIRIT OF
21 THE LAW IS EMBODIED IN THE ACTUAL PROPOSITION AND
22 THEY FOLLOW THAT. THANK YOU.

23 CHAIRMAN CHIANG: THANK YOU. ANY OTHER
24 ADDITIONAL PUBLIC COMMENT?

25 IF NOT, THEN LET'S GO TO THE NEXT ITEM,

BARRISTERS' REPORTING SERVICE

1 ITEM 8, CIRM'S RESPONSE TO THE BSA AUDIT. LET ME
2 INVITE TAMAR FROM CIRM TO ADDRESS THIS ITEM, PLEASE.

3 MS. PACHTER: GOOD AFTERNOON, EVERYONE.
4 THANK YOU. LET ME HAND THESE OUT JUST IN CASE, WITH
5 YOUR PERMISSION. I HAVE FIVE COPIES OF THE SLIDES
6 IN CASE THE TECHNOLOGY FAILS. DOES EVERYBODY HAVE A
7 COPY?

8 SO I'M HERE THIS AFTERNOON TO HELP YOU
9 REVIEW CIRM'S --

10 CHAIRMAN CHIANG: TAMAR, IF YOU PROVIDE
11 YOUR FULL NAME FOR THE RECORD.

12 MS. PACHTER: YES. MY NAME IS TAMAR
13 PACHTER, AND I'M THE GENERAL COUNSEL FOR THE AGENCY,
14 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE.
15 THANK YOU.

16 FIRST, I WANTED TO GO OVER WITH YOU
17 BRIEFLY THE SCOPE OF THE AUDIT THAT THE BUREAU OF
18 STATE AUDITS DID OF CIRM. THE SCOPE IS TO REVIEW
19 THE IMPLEMENTATION OF PROPOSITION 71 AND THE
20 PERFORMANCE OF BOTH CIRM AND THE ICOC, TO REVIEW AND
21 EVALUATE THE STRATEGIC PLAN AND RELATED POLICIES
22 ACCORDING TO BEST PRACTICES, TO REVIEW AND EVALUATE
23 CIRM'S POLICIES AND PROCEDURES, AND TO REVIEW AND
24 EVALUATE MANAGEMENT CONTROLS AND INTERNAL OVERSIGHT
25 STRUCTURE OF CIRM AND THE ICOC.

BARRISTERS' REPORTING SERVICE

1 SO YOU CAN SEE THE SCOPE OF THE BSA'S
2 AUDIT WAS EXTREMELY BROAD. THE JOINT LEGISLATIVE
3 AUDIT COMMITTEE REQUESTED THE AUDIT IN 2006. THE
4 BSA CAME TO CIRM AND COMPLETED ITS AUDIT AND ISSUED
5 ITS REPORT ON FEBRUARY 27, 2007.

6 CIRM PROVIDED RESPONSES TO THE ORIGINAL
7 AUDIT AT 60 DAYS, SIX MONTHS, AND ONE YEAR TO UPDATE
8 THE BSA ON OUR PROGRESS ON IMPLEMENTING THE
9 RECOMMENDATIONS OF THE AUDIT. OUR FINAL RESPONSE
10 WAS SUBMITTED ON FEBRUARY 26, 2008.

11 AT ONE YEAR WE REPORTED TO THE BSA THAT
12 ALL RECOMMENDATIONS OF THE AUDIT WERE IMPLEMENTED OR
13 OTHERWISE RESOLVED. THE BSA HAS NOT COME BACK TO US
14 AND SOUGHT ANY FURTHER RESPONSE FROM CIRM OR
15 RETURNED TO CIRM FOR FURTHER AUDIT.

16 SO NOW I JUST WANT TO TAKE YOU THROUGH
17 BRIEFLY, BUT ONE BY ONE, THE RECOMMENDATIONS OF THE
18 BSA'S AUDIT AND HOW WE IMPLEMENTED THEM.

19 THE FIRST RECOMMENDATION WAS TO PROVIDE
20 ACCOUNTABILITY AND ASSESS ANNUAL PROGRESS IN MEETING
21 THE STRATEGIC GOALS AND INITIATIVES. THE INSTITUTE
22 SHOULD FULFILL ITS PLANS TO DEVELOP A PROCESS TO
23 TRACK MANAGEMENT INFORMATION REPORTED ANNUALLY BY
24 GRANTEES.

25 SO WE HAD THREE WAYS IN WHICH WE

BARRISTERS' REPORTING SERVICE

1 IMPLEMENTED THIS RECOMMENDATION. THE FIRST AND MOST
2 IMPORTANT AND MOST EXPENSIVE WAS GOING THROUGH THE
3 PROCESS TO ENGAGE IN A CONTRACT OF OVER HALF A
4 MILLION DOLLARS TO PUT INTO PLACE AN ELECTRONIC
5 GRANTS MANAGEMENT SYSTEM THAT IS CURRENTLY BEING
6 ROLLED OUT AT CIRM AND IS EXPECTED TO BE COMPLETED
7 IN THE FALL OF THIS YEAR.

8 WE ALSO PUT INTO PLACE, WHICH WAS PART OF
9 THE STRATEGIC PLAN, ANNUAL PROGRESS AND FINANCIAL
10 REPORTING THAT IS REQUIRED OF ALL OUR GRANTEES.
11 THAT IS, THEY HAVE TO REPORT TO US BOTH ON THE
12 PROGRESS OF THE SCIENCE AND ON HOW THEY'RE MEETING
13 THE FINANCIAL EXPECTATIONS OF THE INSTITUTE IN TERMS
14 OF THEIR BUDGET AND HOW THEY'RE USING THE FUNDS THAT
15 WE PROVIDE.

16 FINALLY, WE PUT INTO PLACE A SERIES OF
17 ANNUAL MEETINGS FOR GRANTEES AND CIRM SCHOLARS AT
18 WHICH THEY CAN REPORT TO EACH OTHER AND SHARE
19 INFORMATION AS WELL AS WITH THE SCIENTISTS ON STAFF
20 ABOUT THE PROGRESS OF THE SCIENCE EACH YEAR. SO
21 THAT RECOMMENDATION WAS FULLY IMPLEMENTED IN THAT
22 WAY.

23 THE SECOND RECOMMENDATION CAME IN TWO
24 PARTS. THE COMMITTEE SHOULD IDENTIFY THE
25 APPROPRIATE STANDARD FOR PROVIDING UNINSURED

BARRISTERS' REPORTING SERVICE

1 CALI FORNI ANS WITH ACCESS TO THERAPI ES, AND IN
2 ADD ITION, SHOULD IDENTIFY PRACTICAL BENCHMARKS FOR
3 DISCOUNT PRICES.

4 IN JULY 2007 WE MARKED THE FINAL ADOPTION
5 OF OUR INTELLECTUAL PROPERTY POLICIES FOR NONPROFIT
6 AND ACADEMIC INSTITUTIONS AND IN FEBRUARY 2008 FINAL
7 ADOPTION OF IP POLICIES THAT APPLY TO FOR-PROFIT
8 ORGANIZATIONS. BOTH POLICIES PROVIDE ACCESS FOR
9 UNINSURED CALI FORNI ANS AND IDENTIFIED THE CALRX
10 SYSTEM AS A BENCHMARK FOR DISCOUNT PRICING. AND I'M
11 SURE THERE ARE OTHERS HERE WHO CAN SPEAK MORE
12 SPECIFICALLY TO THOSE ISSUES IF THE COMMITTEE HAS
13 QUESTIONS ABOUT THAT.

14 WITH REGARD TO THE THIRD RECOMMENDATION,
15 WHICH WAS THAT THE COMMITTEE SHOULD MONITOR THE
16 EFFECTIVENESS OF THIS POLICY TO MAKE
17 INSTITUTE-FUNDED, PATENTED INVENTIONS READILY
18 ACCESSIBLE ON REASONABLE TERMS TO OTHER GRANTEE
19 ORGANIZATIONS FOR NONCOMMERCIAL PURPOSES TO ENSURE
20 THAT IT DOES NOT INHIBIT THE ADVANCE OF STEM CELL
21 RESEARCH. THIS WAS A BASIC PRINCIPLE OF OUR
22 STRATEGIC PLAN. AND, IN FACT, THE IP REGULATIONS
23 THAT WERE ADOPTED REQUIRE CIRM GRANTEES TO GIVE
24 OTHER RESEARCHERS ACCESS TO BIOMEDICAL MATERIALS
25 THAT THEY DISCUSS IN THEIR PUBLISHED RESEARCH AT

BARRISTERS' REPORTING SERVICE

1 COST FOR NONCOMMERCIAL PURPOSES.

2 CIRM MONITORS COMPLIANCE WITH THESE IP
3 REGULATIONS THROUGH ANNUAL PROGRESS REPORTING AND
4 COMPLIANCE CHECKS.

5 THE FOURTH RECOMMENDATION OF THE BSA AUDIT
6 STATED THAT THE INSTITUTE SHOULD COMPLETE THE
7 DEVELOPMENT OF ITS GRANTS ADMINISTRATION POLICY
8 TARGETED TOWARD FOR-PROFIT ORGANIZATIONS. AND IN
9 DECEMBER 2007, THE ICOC ADOPTED AN INTERIM GRANTS
10 ADMINISTRATION POLICY FOR FOR-PROFIT ORGANIZATIONS
11 THAT WAS BASED LARGELY ON THE ONE THAT WE HAD PUT IN
12 PLACE FOR NONPROFIT AND ACADEMIC ORGANIZATIONS WITH
13 CHANGES THAT MADE SENSE FOR THE FOR-PROFITS.

14 THE PERMANENT REGULATIONS ARE IN THE OAL
15 PROCESS, AND THE FIRST GRANT TO A FOR-PROFIT WAS
16 AWARDED AT THE JUNE ICOC MEETING. AND THAT AWARD
17 CAME IN THE DISEASE TEAM PLANNING GRANTS.

18 AS ITS FIFTH RECOMMENDATION --

19 MS. KING: THE T.V.'S ARE WORKING. WE'RE
20 JUST TRYING TO GET THEM ON THE SCREEN. THE T.V.'S
21 ARE WORKING, SO THE MEMBERS OF THE PUBLIC CAN
22 ACTUALLY SEE THE SLIDES. WE'RE JUST TRYING TO GET
23 THEM UP ON THE SCREEN.

24 MS. PACTER: LET ME GO ON WITH THE FIFTH
25 RECOMMENDATION. BSA'S FIFTH RECOMMENDATION WAS THAT

BARRISTERS' REPORTING SERVICE

1 THE INSTITUTE SHOULD ENSURE THAT THE GRANTS REVIEW
2 WORKING GROUP FOLLOWS THE NEW PROCEDURES TO RECORD
3 ITS VOTES TO RECOMMEND FUNDING FOR STEM CELL
4 RESEARCH GRANTS AND TO MAINTAIN THOSE RECORDS.
5 INDEED, BEFORE ISSUANCE OF THE AUDIT REPORT, CIRM
6 HAD LISTENED TO THE BSA'S RECOMMENDATIONS AND
7 ADOPTED NEW PROCEDURES TO RECORD THE VOTE, TO
8 IDENTIFY MEMBERS OF THE GRANTS WORKING GROUP WHO
9 WERE RECUSED FROM VOTING, AND TO MAINTAIN THOSE
10 RECORDS FOR AUDIT PURPOSES.

11 THE NAMES OF THE GRANTS WORKING GROUP
12 MEMBERS RECUSED FROM PARTICIPATING IN DISCUSSIONS OF
13 PARTICULAR APPLICATIONS ARE PUBLICLY DISCLOSED AND
14 ARE AN AUDITABLE PART OF THE PUBLIC RECORD AND HAVE
15 BEEN FOR MORE THAN A YEAR.

16 THE BSA'S SIXTH RECOMMENDATION WAS THAT
17 THE INSTITUTE SHOULD COMPLETE THE IMPLEMENTATION OF
18 A GRANTS MONITORING PROCESS, INCLUDING AUDITS, AND
19 THE DEVELOPMENT OF RELATED PROCEDURES. CIRM HAS IN
20 PLACE WRITTEN PROCEDURES FOR ADMINISTRATIVE REVIEW
21 OF GRANTS AWARDED AND INTERNAL AUDIT OF THAT
22 PROCESS. IN ADDITION, WE HAVE WRITTEN PROCEDURES
23 FOR MILESTONES ON CAPITAL GRANTS, THOSE GRANTS, IF
24 YOU SEE THESE BEAUTIFUL PICTURES OF THE BUILDINGS
25 THAT CIRM IS HELPING TO BUILD AROUND THE STATE. WE

BARRISTERS' REPORTING SERVICE

1 ALSO HAVE WRITTEN PROCEDURES FOR MONITORING GRANTEE
2 COMPLIANCE WITH REGULATIONS, AND WE HAVE AUDIT
3 PROCEDURES FOR SPOT-CHECKING TO MAKE SURE THAT THEY
4 ARE, IN FACT, IN COMPLIANCE.

5 THE BSA'S SEVENTH RECOMMENDATION WAS THAT
6 THE INSTITUTE SHOULD SEEK A FORMAL OPINION FROM THE
7 AG REGARDING WHETHER THE EXCEPTIONS CREATED FOR
8 WORKING GROUPS FROM CONFLICT OF INTEREST LAWS ARE
9 INTENDED TO EXEMPT THEM IF THE RECOMMENDATIONS OF
10 THE WORKING GROUP ARE ROUTINELY AND REGULARLY
11 ADOPTED.

12 AND ONE OF THE THINGS THAT THE BSA NOTED
13 IN THE AUDIT WAS THAT AT THE TIME WE HAD A DECISION
14 FROM THE STATE TRIAL COURT SAYING THAT THE ICOC WAS
15 THE FINAL DECISION MAKER; AND, THEREFORE, THERE WAS
16 NO REASON THAT THE STATE CONFLICT OF INTEREST LAWS
17 WOULD APPLY TO AN ADVISORY BODY. SINCE THAT TIME,
18 WE HAVE HAD A DECISION FROM THE COURT OF APPEAL
19 AFFIRMING THAT DECISION OF THE SUPERIOR COURT AND
20 HOLDING THAT THE ICOC, NOT THE WORKING GROUPS,
21 EXERCISE ALL DECISION-MAKING AUTHORITY. AND THE
22 SUPREME COURT, WHEN ASKED TO REVIEW, DENIED REVIEW
23 OF THAT DECISION ON MAY 16, 2007.

24 SO WE NOW HAVE BINDING LEGAL AUTHORITY
25 THAT THE CONFLICT OF INTEREST RULES THAT ARE

BARRISTERS' REPORTING SERVICE

1 GENERALLY APPLICABLE TO PUBLIC OFFICIALS IN
2 CALIFORNIA DO NOT APPLY TO THE MEMBERS OF OUR
3 WORKING GROUPS BECAUSE THEY ARE NOT DECISION MAKERS.

4 THE NEXT RECOMMENDATION WAS THAT THE
5 INSTITUTE SHOULD AMEND ITS CONFLICT OF INTEREST
6 POLICIES TO INCLUDE SPECIALISTS INVITED TO
7 PARTICIPATE IN GRANT APPLICATION REVIEW. I SHOULD
8 EXPLAIN THAT SPECIALISTS ARE SCIENTISTS WHO, AS
9 SUZANNE MENTIONED EARLIER, WHO PARTICIPATE WITH
10 RESPECT TO SPECIFIC APPLICATIONS ABOUT WHICH THEY
11 HAVE SPECIFIC EXPERTISE. THEY DON'T VOTE IN THE
12 GRANTS WORKING GROUP, BUT THEY DO PARTICIPATE IN THE
13 MEETINGS BY PHONE, REVIEW THE APPLICATIONS IN THEIR
14 AREAS OF EXPERTISE.

15 AND WE HAD ALWAYS TREATED THEM JUST LIKE
16 ANY OTHER MEMBERS OF THE WORKING GROUP WITH RESPECT
17 TO OUR CONFLICTS OF INTEREST POLICY, BUT THE BSA
18 POINTED OUT THAT OUR CONFLICT OF INTEREST POLICY
19 SHOULD STATE SO SPECIFICALLY. AND SO IN MARCH OF
20 2007, THE ICOC AMENDED THE CONFLICT OF INTEREST
21 POLICY FOR THE GRANTS WORKING GROUP TO SPECIFICALLY
22 INCLUDE BOTH SPECIALISTS AND AD HOC MEMBERS, WHICH
23 ARE ANOTHER FORM OF TEMPORARY MEMBER OF THE GRANTS
24 WORKING GROUP.

25 THE BSA ALSO RECOMMENDED ITS NINTH

BARRISTERS' REPORTING SERVICE

1 RECOMMENDATION, WHICH WAS THAT THE INSTITUTE SHOULD
2 DEVELOP PROCEDURES TO ENSURE THAT ITS EMPLOYEES ARE
3 AWARE OF THE COMPANIES THAT APPLY FOR FUNDING.
4 THESE ARE FOR-PROFIT COMPANIES. AND WELL IN ADVANCE
5 OF THE FIRST RFA IN WHICH FOR-PROFIT ORGANIZATIONS
6 WERE ELIGIBLE TO APPLY, WE HAD A PROCESS IN PLACE
7 THAT HAS BEEN USED TO NOTIFY EMPLOYEES OF THE NAMES
8 OF COMPANIES. FIRST ONE THEY SUBMIT WHAT WE CALL
9 LOI'S OR LETTERS OF INTENT IN ADVANCE OF SUBMITTING
10 THEIR APPLICATION AND THEN AGAIN WHEN THEY SUBMIT
11 THEIR APPLICATIONS SO THAT EMPLOYEES CAN IDENTIFY
12 ANY FINANCIAL CONFLICTS OF INTEREST THAT THEY MAY
13 HAVE WITH ANY OF THE COMPANIES THAT APPLY.

14 WE ALSO GO TO GREAT LENGTHS TO MAINTAIN
15 THE CONFIDENTIALITY OF THOSE NAMES, BUT THAT
16 INFORMATION IS CERTAINLY AVAILABLE FOR AUDIT.

17 THE TENTH RECOMMENDATION OF THE BSA WAS
18 THAT THE INSTITUTE SHOULD REVIEW THE STATEMENTS OF
19 ECONOMIC INTEREST FOR COMMITTEE MEMBERS, THUS
20 MEMBERS OF THE ICOC, AND THE WORKING GROUPS BEFORE
21 EVERY GRANTS REVIEW MEETING AND ENSURE THAT IT
22 RETAINS DOCUMENTATION REGARDING THE CONFLICTS OF
23 INTEREST OF THE WORKING GROUPS, INCLUDING
24 INFORMATION THAT IT TOOK APPROPRIATE RECUSAL
25 ACTIONS.

BARRISTERS' REPORTING SERVICE

1 SINCE NOVEMBER OF 2006, THIS WAS MONTHS
2 BEFORE THE BSA AUDIT WAS PUBLISHED, STAFF HAS
3 PERFORMED A BACKUP REVIEW OF ALL WORKING GROUP
4 MEMBERS, INCLUDING MEMBERS OF THE ICOC, BY COMPARING
5 THEIR PREMEETING CONFLICT OF INTEREST DISCLOSURES
6 WITH THEIR STATEMENTS OF ECONOMIC INTEREST TO MAKE
7 SURE THAT THEY ARE CONSISTENT AND HAS DOCUMENTED
8 RECUSALS DURING THE MEETING TO MAKE SURE THAT
9 MEMBERS WHO HAVE A CONFLICT OF INTEREST WITH RESPECT
10 TO A PARTICULAR APPLICATION LEAVE THE ROOM DURING
11 DISCUSSION AND VOTING OF THAT APPLICATION. AND THAT
12 IS DOCUMENTED BY STAFF AND MAINTAINED AS A PERMANENT
13 RECORD OF THE MEETING.

14 THE BSA'S NEXT RECOMMENDATION WAS THAT THE
15 INSTITUTE SHOULD ENSURE THAT IT FOLLOWS ITS NEWLY
16 REVISED POLICIES AND SHOULD ALSO AMEND ITS POLICIES
17 FURTHER TO INCLUDE THE REST OF THE CONCERNS THAT WE
18 HAVE RAISED. SPECIFICALLY, THE INSTITUTE SHOULD
19 IMPLEMENT A PREAPPROVAL REQUIREMENT FOR TRAVELERS
20 THAT WANT TO CLAIM MEALS SEPARATELY.

21 SO WHAT THE BSA WAS TALKING ABOUT HERE WAS
22 OUR TRAVEL AND EXPENSE POLICIES. AND WE HAVE A
23 TRAVEL POLICY AND A BUSINESS MEETING EXPENDITURE
24 POLICY THAT CLOSELY CONFORM TO THOSE THAT THE UC
25 USES. WE ALTERED THEM IN SOME RESPECTS, BECAUSE THE

BARRISTERS' REPORTING SERVICE

1 UC IS A MUCH BIGGER INSTITUTION, TO MAKE THEM MAKE
2 SENSE FOR OUR ORGANIZATION, BUT GENERALLY THEY
3 ADHERE TO THE FORMAT YOU WILL SEE AT UC. AND WE
4 REPORTED TO BSA THAT EMPLOYEES ARE NEVER REIMBURSED
5 FOR MEALS AT MEETINGS WHERE MEALS ARE PROVIDED
6 WITHOUT PRIOR AUTHORIZATION BY THE PRESIDENT.

7 THE NEXT TWO RECOMMENDATIONS OF THE BSA
8 ALSO WENT TO TRAVEL REIMBURSEMENT.

9 CHAIRMAN CHIANG: HOW MANY INSTANCES DID
10 THAT TAKE PLACE.

11 MS. PACHTER: PARDON ME?

12 CHAIRMAN CHIANG: HOW MANY INSTANCES DID
13 THAT TAKE PLACE?

14 MS. PACHTER: YOU KNOW, I CAN'T TELL YOU
15 OFF THE TOP OF MY HEAD. I THINK THE BSA POINTED TO
16 LESS THAN A HANDFUL OF INSTANCES IN WHICH THAT HAD
17 HAPPENED THAT THEY FOUND DURING THE COURSE OF THEIR
18 AUDIT, AND IT HAS NOT HAPPENED SINCE NOVEMBER OF
19 2006.

20 CHAIRMAN CHIANG: I'M SORRY. WHAT HAS NOT
21 HAPPENED?

22 MS. PACHTER: IN OTHER WORDS, EMPLOYEES --
23 IF WE'RE PROVIDING MEALS AT MEETINGS --

24 CHAIRMAN CHIANG: I UNDERSTAND. I DIDN'T
25 PHRASE THE QUESTION PROPERLY. I'LL GIVE YOU A

BARRISTERS' REPORTING SERVICE

1 BETTER SENSE. SO HAVE THERE BEEN ANY PRIOR
2 AUTHORIZATIONS TO REQUESTS THAT WOULD INVOLVE PRIOR
3 AUTHORIZATIONS, OR HAVE THERE BEEN NO REQUESTS SINCE
4 THE POLICY HAS BEEN CHANGED?

5 MS. PACHTER: YOU KNOW, I'LL HAVE TO ASK
6 MARGARET.

7 MS. FERGUSON: NO, THERE HAVE NOT BEEN ANY
8 REQUESTS FOR PRIOR AUTHORIZATION FOR MEALS. WHERE
9 THE INSTITUTE PROVIDED THE MEAL, FOR SOMEONE TO
10 CLAIM IT SEPARATELY, NO. THE ANSWER IS NO.

11 CHAIRMAN CHIANG: THANK YOU.

12 MS. PACHTER: SO THE BSA RECOMMENDED THAT
13 THE INSTITUTE REVISE THE TRAVEL REIMBURSEMENT CLAIMS
14 FORM, THE ONE THAT WAS USED BY WORKING GROUP
15 MEMBERS, TO REQUIRE SUFFICIENT INFORMATION THAT
16 WOULD ALLOW AN ADEQUATE REVIEW OF THE AMOUNTS
17 CLAIMED. AND SINCE MARCH 1ST OF LAST YEAR, THE
18 WORKING GROUP MEMBERS HAVE ALL SUBMITTED THEIR
19 TRAVEL REIMBURSEMENT CLAIMS ON THE STANDARD STATE
20 TRAVEL FORM. IT'S USED BY EMPLOYEES AND IT'S USED
21 BY WORKING GROUP MEMBERS.

22 THE BSA ALSO RECOMMENDED THAT THE ICOC
23 ADOPT A TRAVEL REIMBURSEMENT POLICY FOR ITS MEMBERS
24 THAT WILL RESULT IN REIMBURSEMENT OF REASONABLE AND
25 NECESSARY EXPENSES. AND WHEN THE BSA AUDIT CAME

BARRISTERS' REPORTING SERVICE

1 OUT, THE ICOC AGREED TO ADHERE TO THE POLICY THAT
2 HAD BEEN PUT IN PLACE FOR STAFF, AND IT DID SO UNTIL
3 JANUARY OF THIS YEAR WHEN WE PUT TOGETHER A SINGLE
4 TRAVEL POLICY. IT APPLIES TO ICOC MEMBERS, WORKING
5 GROUP MEMBERS, AND EMPLOYEES AND COVERS US ALL
6 EQUALLY.

7 THE LAST RECOMMENDATION OF THE BSA WAS
8 THAT THE INSTITUTE SHOULD FOLLOW THROUGH WITH ITS
9 PLAN TO RESURVEY ANY POSITION WHOSE SALARY RANGES
10 WERE AFFECTED BY ERRORS, OMISSIONS, AND
11 INCONSISTENCIES IN ITS INITIAL SALARY SURVEY AND
12 SALARY SETTING ACTIVITIES.

13 CIRM DID COMMISSION A NEW SALARY SURVEY
14 FROM MERCER. IT WAS A REPORT THAT, I BELIEVE, WAS
15 REVIEWED BY THE CONTROLLER'S OFFICE DURING ITS
16 AUDIT, AND WE RECEIVED THE REPORT IN JANUARY OF THIS
17 YEAR. THE ICOC HAS APPROVED CHANGES IN SALARY
18 RANGES CONSISTENT WITH THE MERCER DATA SINCE THAT
19 TIME.

20 AND IF YOU HAVE ANY QUESTIONS, I'M HAPPY
21 TO ANSWER THEM.

22 CHAIRMAN CHIANG: VERY GOOD. ARE THERE
23 ANY QUESTIONS?

24 DR. LIPSON: YES. I AM INTERESTED IN YOUR
25 CAPITAL GRANTS. ONE OF THE THINGS THAT I SAW AND

BARRISTERS' REPORTING SERVICE

1 HAVE SEEN, BEING AT SEVERAL MAJOR UNIVERSITIES AND
2 MEDICAL SCHOOLS AND HOSPITALS THAT DO A LOT OF
3 RESEARCH, IS STATE RESEARCH SPACE IS VERY LIMITED
4 AND VERY SOUGHT AFTER. WHAT PROVISIONS HAVE BEEN
5 MADE IN GIVING THESE GRANTS THAT WHEN SPACE IS NOT
6 USED FOR STEM CELL RESEARCH, THAT THE CITIZENS OF
7 THE STATE OF CALIFORNIA REIMBURSE FOR THE MONIES PUT
8 INTO THESE INSTITUTIONS TO PROVIDE THEM MORE SPACE
9 WHICH WAS SUPPOSED TO BE USED FOR STEM CELL
10 RESEARCH?

11 MS. PACHTER: I THINK CHAIRMAN KLEIN WOULD
12 LIKE TO ANSWER YOUR QUESTION.

13 MR. KLEIN: YES, MEMBER LIPSON.
14 SPECIFICALLY, AS A REQUIREMENT FOR COMPETING FOR OUR
15 GRANTS, WE CREATED A PROVISION THAT REQUIRED THAT
16 FOR THE TEN YEARS APPROXIMATELY FOR WHICH WE WILL
17 HAVE FUNDING FOR STEM CELL RESEARCH, THAT THESE
18 INSTITUTIONS THAT BUILD THESE FACILITIES HAVE TO
19 DEDICATE THEM TO STEM CELL RESEARCH FOR THE ENTIRE
20 TEN-YEAR PERIOD. SO THEY ARE RESTRICTED TO USING
21 THEM FOR STEM CELL RESEARCH AND WHAT'S CALLED OTHER
22 VITAL RESEARCH OPPORTUNITIES THAT RELATES DIRECTLY
23 TO STEM CELL RESEARCH. FOR EXAMPLE, YOU MAY LOOK AT
24 THE NICHE IN WHICH STEM CELLS ORIGINATE IN THE BONE
25 MARROW FOR ADULT STEM CELL STUDIES.

BARRISTERS' REPORTING SERVICE

1 DR. LIPSON: WHAT OVERSIGHT DO YOU HAVE TO
2 MAKE SURE THEY'RE INDEED USING THAT SPACE FOR STEM
3 CELL RESEARCH? I'VE SEEN TIME AND TIME AGAIN SPACE
4 USED FOR THINGS THAT HAVE NOTHING TO DO WITH WHAT
5 THEY WERE SUPPOSED TO BE BUILT FOR.

6 MR. KLEIN: SURE. WE'VE INSTITUTED AN
7 INSPECTION PROCESS THAT DEALS WITH BOTH FINANCIAL
8 AND MEDICAL AND ETHICAL OVERSIGHT FOR OUR GRANT
9 PROGRAM. AND ALL OF OUR MAJOR FACILITIES ARE
10 CURRENTLY IN PROGRESS OF CONSTRUCTION. SO THEY WILL
11 BE COMPLETED ABOUT JULY OF 2010, BUT THE PROGRAM IS
12 DESIGNED TO FOLLOW UP AND ENSURE THAT, IN FACT, THEY
13 ARE USING THE SPACE FOR STEM CELL RESEARCH.

14 DR. LIPSON: HOW IS THAT GOING TO BE DONE?

15 MR. KLEIN: WITH A REPORTING SYSTEM AS
16 WELL AS ON-SITE INSPECTIONS, BOTH.

17 DR. LIPSON: I THINK ON-SITE INSPECTION IS
18 PROBABLY A KEY.

19 MR. KLEIN: ON-SITE INSPECTIONS ARE
20 CERTAINLY AN ESSENTIAL, ABSOLUTELY.

21 MR. CHAIRMAN, IF I COULD ALSO SUPPLEMENT
22 THE COMMENTS OF OUR COUNSEL ON THE RESPONSE TO
23 RECOMMENDATION NO. 2.

24 RECOMMENDATION NO. 2 IS VERY IMPORTANT
25 BECAUSE IT RELATED TO ACCESS TO FUTURE TREATMENTS.

BARRISTERS' REPORTING SERVICE

1 AND ONE OF OUR PROBLEMS WITH SENATE BILL 1565, MY
2 UNDERSTANDING IS THAT SENATOR KUEHL IS GOING TO
3 AMEND THE BILL TO ADDRESS, RELATES TO ACCESS BECAUSE
4 IT ISN'T ENOUGH JUST TO CREATE THERAPIES. WE HAVE
5 TO GET THEM TO THE PATIENTS. AND IN PARTICULAR
6 WHERE WE HAVE ORPHAN DISEASES, WHERE UNDER THE
7 FEDERAL DEFINITION IT'S LESS THAN 200,000 CASES,
8 THESE MAY BE VERY EXPENSIVE. AND IT'S DIFFICULT TO
9 SET RIGID PRICE BENCHMARKS FOR THERAPIES THAT YOU
10 HAVEN'T SEEN YET, FOR DISEASES THAT YOU HAVEN'T
11 IDENTIFIED YET.

12 AND SO OUR PROBLEM IN THE AGENCY BOARD OF
13 ALL 29 MEMBERS UNANIMOUSLY OPPOSING THE BILL AT THIS
14 TIME WAS THAT THEY SET THREE DIFFERENT PRICE
15 GUIDELINES THAT WE HAVE ADOPTED IN OUR OWN
16 REGULATIONS AS BASIC BENCHMARKS. BUT UNDER OUR
17 REGULATORY PROCESS, WE WOULD RIGHT NOW HAVE THE
18 ABILITY TO MODIFY THESE PRICING BENCHMARKS TO ADAPT
19 TO THE VERY SPECIFIC SITUATION. AND THERE CAN BE
20 SUBCLASSES EVEN WITHIN MAJOR DISEASES THAT NEED
21 SPECIAL ATTENTION.

22 FOR EXAMPLE, IN ORDER TO ASSURE ACCESS IN
23 ALZHEIMER'S, WE NEED TO REALIZE THAT, ALTHOUGH MOST
24 OF THE CASES HAVE LATE ONSET IN THEIR 70S, THERE IS
25 A GROUP OF ALZHEIMER'S PATIENTS THAT HAVE ONSET IN

BARRISTERS' REPORTING SERVICE

1 THEIR 50S, A SMALL GROUP, BUT IT'S A DEVASTATED
2 GROUP, THAT IN VERY HIGH PERCENTAGES MAY NEED
3 ASSISTANCE.

4 RIGHT NOW THE BILL AS IT'S WRITTEN WOULD
5 ONLY PROVIDE US WITH THE ABILITY TO MAKE A PRICE FOR
6 THE ENTIRE ALZHEIMER'S THERAPY; WHEREAS, IN FACT, WE
7 MAY NEED TO SET OUR PRICES A LITTLE HIGHER. THIS IS
8 FOR PUBLIC AGENCIES. WE MAY SET OUR PRICE A LITTLE
9 HIGHER FOR THOSE PEOPLE THAT ARE COVERED BY MEDICARE
10 WHO ARE IN THEIR 70S, AND, IN FACT, REQUIRE THE
11 PRIVATE FIRM TO USE THAT ADDITIONAL MONEY TO
12 SUBSIDIZE DOWN THE PRICE FOR THOSE WITH EARLY ONSET
13 WHO ARE IN DESPERATE NEED, IN FACT, MAY BE LOSING
14 THEIR JOB AND HAVE COMPLICATIONS WITH THEIR FAMILY
15 BECAUSE OF THE DEVASTATING IMPACT OF A DISEASE LIKE
16 THIS HITTING BEFORE THEIR PENSIONS, FOR EXAMPLE, ARE
17 FULLY VESTED. SO IT HAS BEEN VERY IMPORTANT TO US
18 TO MAKE SURE WE'RE PROVIDING THE RIGHT THERAPIES.

19 THERE IS A CLINICAL TRIAL GOING ON RIGHT
20 NOW IN OREGON FOR BATTEN'S DISEASE. IT'S A TRAGIC
21 DISEASE THAT DESTROYS THE BRAIN OF YOUNG CHILDREN.
22 WE'VE MET WITH THE INDIVIDUALS AT STANFORD WHO HAVE
23 LEFT STANFORD AND JOINED A COMPANY THAT IS
24 CONDUCTING THESE CLINICAL TRIALS. THEIR COUNSEL HAS
25 ADVISED THEM THAT WITH OUR PRICING REGIMES, WITHOUT

BARRISTERS' REPORTING SERVICE

1 THE ABILITY TO FULLY RESPOND TO ORPHAN DISEASES,
2 THAT THEY CANNOT APPLY FOR OUR GRANTS EVEN THOUGH
3 THEY DESPERATELY NEED IT BECAUSE THIS NOT AN AREA
4 WHERE YOU CAN GET COMMERCIAL MONEY FOR THIS SMALL
5 ORPHAN DISEASE.

6 SO, YOU KNOW, IT WOULD BE A TREMENDOUS
7 TRAGEDY IF, IN FACT, THERE IS A THERAPY THAT PROVES
8 OUT IN THESE CLINICAL TRIALS, AND YET WE'RE NOT ABLE
9 TO MOVE IT FROM THE PHASE I CLINICAL TRIALS WITH
10 SHOWING OF EFFICACY TO FULL PHASE II AND PHASE III
11 TRIALS BECAUSE THEY CAN'T ACCEPT OUR MONEY BECAUSE
12 WE LACK THE FLEXIBILITY.

13 ANY CHANGE TO THESE REGULATIONS WOULD HAVE
14 TO BE DONE IN A PUBLIC HEARING THAT'S ALREADY PART
15 OF OUR REGULATIONS. SO IT'S AN OPEN, TRANSPARENT
16 PROCESS. BUT BY BEING ABLE TO CHANGE AND ADAPT EACH
17 THERAPY AND EACH DISEASE IN PUBLIC HEARINGS IN A
18 PUBLIC FORMAT THAT'S JUSTIFIED, WE BELIEVE THAT
19 PROVIDES THE BEST OPPORTUNITY TO SERVE PATIENTS.
20 AND TO HAVE A RIGID FORMULA FOR PRICES WILL FORCE
21 AWAY CAPITAL THAT'S ESSENTIAL FOR US TO GET THE
22 PRIVATE SECTOR INVOLVED TO DELIVER THERAPIES TO
23 PATIENTS.

24 SO AS A PART OF OUR RESPONSIBILITY TO
25 DEVELOP REAL ACCESS FOR PATIENTS, WE WOULD LIKE TO

BARRISTERS' REPORTING SERVICE

1 FOCUS EVERYONE ON THE NECESSITY FOR A REGULATORY
2 PROCESS BECAUSE TO AMEND LEGISLATION TAKES A
3 70-PERCENT VOTE AND THE SIGNATURE OF THE GOVERNOR, A
4 YEAR'S DELAY. IN ALS YOU ONLY HAVE THREE YEARS OF
5 LIFE AFTER YOU'RE DIAGNOSED ON AVERAGE. IN BATTEN'S
6 DISEASE, IF YOU DON'T INTERVENE EARLY, YOU MAY LOSE
7 THE OPPORTUNITY TO RESPOND. SO IT IS VERY IMPORTANT
8 THAT WE HAVE A FLEXIBLE PROCESS THROUGH REGULATION
9 WHERE WE CAN RESPOND.

10 MY UNDERSTANDING IS THAT SENATOR KUEHL IS
11 GOING TO TRY AND RESPOND TO THIS WITH AMENDMENTS,
12 WHICH WE THINK ARE VERY CRITICAL AND VERY ESSENTIAL
13 TO PROVIDE REAL ACCESS. BUT THANK YOU VERY MUCH.

14 CHAIRMAN CHIANG: ADDITIONAL QUESTIONS?

15 DR. LIPSON: I DO HAVE SOME QUESTIONS
16 ABOUT YOUR 15 SCIENTISTS YOU USE AS REVIEWERS WHO
17 ARE OUTSIDE THE STATE AND WHAT INTERACTIONS THEY
18 HAVE HAD IN THE PAST WITH PEOPLE WHOSE GRANTS
19 THEY'RE REVIEWING PRESENTLY OR IN THE FUTURE AND
20 WITH THE DISCUSSION OF HOW PEOPLE ARE FLOCKING TO
21 THE STATE BECAUSE THERE IS MONEY FOR STEM CELL
22 RESEARCH. MIGHT NOT SOME OF THESE PEOPLE BE SETTING
23 UP PROGRAMS THAT THEY THEMSELVES WILL BE ABLE TO
24 TAKE ADVANTAGE OF AS RESEARCHERS?

25 MS. PACTER: OUR CONFLICT OF INTEREST

BARRISTERS' REPORTING SERVICE

1 POLICY, DR. LIPSON, HAS THREE PARTS. IT PROHIBITS
2 FINANCIAL PERSONAL AND PROFESSIONAL CONFLICTS OF
3 INTEREST. SO A MEMBER OF OUR REVIEW TEAM WHO IS IN
4 NEGOTIATIONS, FOR INSTANCE, TO COME AND WORK FOR A
5 UNIVERSITY IN CALIFORNIA COULD NO LONGER BE A MEMBER
6 OF OUR REVIEW TEAM. SO IF THAT'S ONE OF YOUR
7 CONCERNS, THAT'S SOMETHING THAT'S STRICTLY
8 PROHIBITED.

9 IT IS TRUE THAT ONE OF THE THINGS THAT
10 PROP 71 WAS TRYING TO DO WAS TO ENCOURAGE
11 RESEARCHERS TO COME TO THE STATE OF CALIFORNIA. BUT
12 WE BELIEVE THAT THE CONFLICT OF INTEREST POLICY THAT
13 WE HAVE IN PLACE PROTECTS US FROM A SITUATION IN
14 WHICH SOMEBODY COULD USE THEIR POSITION ON THE
15 GRANTS REVIEW WORKING GROUP TO LEVERAGE A POSITION
16 HERE IN CALIFORNIA. IS THAT WHAT YOUR CONCERN IS?

17 DR. LIPSON: THAT'S PART OF IT. OTHER
18 PARTS ARE THAT INDIVIDUALS WHO MAY NOT HAVE BEEN
19 ABLE TO MAKE IT IN STRICT COMPETITION FOR GRANTS CAN
20 COME TO THIS STATE. AND IF THEY FIND A POSITION,
21 THEY MAY BE ABLE TO GET A POSITION WHICH THEY'RE
22 MAYBE NOT AS ADEPT AT DOING RESEARCH AS THEY SHOULD
23 BE.

24 MR. KLEIN: YOU HAVE A VERY FAMOUS NAME
25 BECAUSE THE CHAIR OF OUR PEER REVIEW IS STUART

BARRISTERS' REPORTING SERVICE

1 LIPSON FROM THE HARVARD STEM CELL CENTER. IF YOU
2 LOOK AT THE NAMES OF OUR PEER REVIEW, AND THEY
3 CHANGE BY AREA, THERE'S 15 PEOPLE THAT RELATE TO
4 THAT SPECIFIC AREA UNDER PEER REVIEW. THEY'RE
5 EXTRAORDINARY RESEARCHERS FROM AROUND THE UNITED
6 STATES AND AROUND THE WORLD BECAUSE, INDEED, WE'VE
7 HAD RESEARCHERS FROM SWEDEN AND ENGLAND COME TO
8 SERVE ON OUR PEER REVIEW, BUT IT IS AN EXTREMELY
9 PRESTIGIOUS GROUP OF INDIVIDUALS.

10 IF YOU EXAMINE THEIR ASSOCIATIONS TOO FROM
11 INSTITUTIONS, YOU WILL SEE THAT THEY ARE FROM
12 EXTRAORDINARILY PREEMINENT INSTITUTIONS IN THE
13 COUNTRY AND THE WORLD. BUT WE HAVE THE SAME
14 CONCERNS THAT YOU DO. AND IN TRYING TO MAKE SURE
15 THAT WE ARE PROTECTED AGAINST THOSE CONCERNS, WHAT
16 OUR COUNSEL JUST REFERRED TO IN TERMS OF
17 PROFESSIONAL CONFLICTS, IF YOU EVEN REVIEWED AN
18 ARTICLE WITH SOMEONE WITHIN THREE YEARS, YOU ARE
19 DISQUALIFIED FROM THAT GRANT REVIEW. IF YOU HAVE
20 MENTORED THEM AS A STUDENT, SO YOU HAVE A PERSONAL
21 OR PROFESSIONAL RELATIONSHIP, YOU ARE DISQUALIFIED
22 FROM THAT GRANT REVIEW. IF YOU HAVE A CLOSE
23 PERSONAL FRIENDSHIP, YOU ARE DISQUALIFIED FROM THAT
24 GRANT REVIEW.

25 SO WE'VE GONE FAR BEYOND, AS THE

BARRISTERS' REPORTING SERVICE

1 CONTROLLER' S STUDY SHOWS, FAR BEYOND THE NIH
2 STANDARDS IN AVOIDING CONFLICTS. AND, IN FACT,
3 SETTING UP THIS PEER REVIEW PROCESS, WE WENT TO THE
4 GENERAL COUNSEL FOR THE NATIONAL ACADEMY OF
5 SCIENCES, MR. WRIGHT, AND GOT HIS RECOMMENDATIONS TO
6 TRY AND ANTICIPATE THE KINDS OF PROBLEMS THAT YOU
7 ARE LOOKING AT.

8 BUT YOUR QUESTION GOES FURTHER, WHICH IS
9 TO SAY CAN SOMEONE ESSENTIALLY PARTICIPATE IN A PEER
10 REVIEW AND SET UP A PROGRAM THEY WOULD THEN
11 PARTICIPATE IN? THE PEER REVIEWERS DON' T GET TO
12 DESIGN PROGRAMS. THEY ONLY CAN RECOMMEND AND SCORE
13 INDIVIDUAL GRANTS. SO THAT THEY CAN APPROVE AN
14 INDIVIDUAL GRANT; THEY CAN' T APPROVE A LONG-TERM
15 PROGRAM THAT THEY WOULD THEN COME AND THEN COMPETE
16 FOR.

17 SO WE' VE TRIED AND WE WOULD WELCOME
18 RECOMMENDATIONS, BUT WE HAVE TRIED TO ANTICIPATE ANY
19 AREA OF CONFLICT POSSIBLE AND AVOID THAT. AND I
20 BELIEVE THAT INSTITUTIONALLY INTERNALLY AT THE
21 NATIONAL INSTITUTES OF HEALTH AND IN THE MAJOR
22 INSTITUTIONS AROUND THE COUNTRY, OUR PROCESS OF
23 CONFLICTS OF INTEREST PROTECTIONS FOR PEER REVIEW
24 ARE BEING REVIEWED HIGHLY AND ARE BEING IMITATED.
25 HOPEFULLY AS THEY IMITATE THEM, THEY' LL GIVE US

BARRISTERS' REPORTING SERVICE

1 FURTHER FEEDBACK TO FURTHER REFINE OUR GOALS AND
2 YOUR GOALS OF MAKING SURE WE ARE REALLY RIGOROUS IN
3 AVOIDING ANY CONFLICTS IN PEER REVIEW.

4 WITH 15 DIFFERENT REVIEWERS, OF COURSE,
5 ONE REVIEWER'S SCORE CAN'T SKEW THE RECOMMENDATION.
6 AND THAT IS ADVISORY AND THEN GOES TO THE FULL
7 BOARD, AND THE BOARD CAN VOTE INDEPENDENTLY FOR OR
8 AGAINST AN APPLICATION, WITH NO ONE ON THE BOARD
9 WHOSE APPLICATION IS UP BEING ABLE TO EITHER DISCUSS
10 IT OR PARTICIPATE IN THE VOTE.

11 DR. LIPSON: I HAVE OTHER QUESTIONS. HOW
12 ARE YOU PROTECTING THE SCIENTISTS AND CALIFORNIA'S
13 IDEAS AND RESEARCH FINDINGS FROM BEING BASICALLY
14 TAKEN BY YOUR REVIEWERS?

15 MR. KLEIN: YES, SIR. WITH THE PEER
16 REVIEW THAT TAKES PLACE AT THE NATIONAL INSTITUTES
17 OF HEALTH AND IN THE MAJOR FOUNDATIONS AROUND THE
18 COUNTRY, WE HAVE A COMMON PROBLEM, WHICH IS WE ALL
19 RECEIVE A SIGNED SWORN STATEMENT OF THOSE REVIEWERS
20 THAT THEY'RE TREATING ALL OF THIS INFORMATION
21 CONFIDENTIALLY AND PROTECTING IT AS THE INTELLECTUAL
22 WORK PRODUCT OF THE REVIEWER.

23 ADDITIONALLY, WHAT WE DO IS THAT IN THE
24 RECOMMENDATION TO THE BOARD, PROPRIETARY INFORMATION
25 IS NOT PART OF THE PUBLIC WRITE-UP. THERE ARE

BARRISTERS' REPORTING SERVICE

1 PUBLIC SUMMARIES THAT GO TO THE BOARD AND FOR THE
2 PUBLIC ON THE BENEFIT TO CALIFORNIA AND A PUBLIC
3 DESCRIPTION OF THE RESEARCH, BUT PROPRIETARY
4 CHEMICAL PROCESSES OR ORGANIC PROCESSES THAT ARE KEY
5 TO THEIR RESEARCH ARE NOT PART OF THAT SUMMARY.

6 THE BOARD INDIVIDUALLY IN EXECUTIVE
7 SESSION, LIMITED TO INDIVIDUALS WHO ARE NOT IN
8 CONFLICT AND SUPERVISED BY COUNSEL ON MY RIGHT,
9 COUNSEL ON MY LEFT, COUNSEL IN THE THIRD ROW BACK,
10 SUPERVISE TO MAKE SURE ONLY THOSE WITHOUT A CONFLICT
11 ON THE BOARD CAN SEE THE PROPRIETARY INFORMATION.
12 BUT THE PROPRIETARY INFORMATION IS PROTECTED BOTH
13 FOR THE BENEFIT OF CALIFORNIA AND FOR THE BENEFIT OF
14 PATIENTS. WE HAVE TO RETAIN THE TRUST OF
15 RESEARCHERS THAT THAT INFORMATION AND THEIR
16 BRILLIANT NEW IDEAS, THEY WILL HAVE A CHANCE TO
17 PROVE OR DISPROVE WITHOUT ENCROACHMENT BY SOMEONE
18 ELSE.

19 DR. LIPSON: BUT, AGAIN, I'VE SEEN
20 SITUATIONS WRITTEN UP IN *NEW YORK TIMES* AND OTHER
21 NEWSPAPERS ABOUT SITUATIONS WHERE A SENIOR SCIENTIST
22 WILL ALLOW A JUNIOR PERSON TO LOOK AT INFORMATION
23 AND ALL OF A SUDDEN A PAPER APPEARS.

24 MR. KLEIN: YES, SIR. TWO THINGS THAT
25 OCCUR. ONE IS THAT WE KEEP RECORDS OF EVERY GRANT

BARRISTERS' REPORTING SERVICE

1 THAT EVERY PEER REVIEWER ACTUALLY GETS TO SEE, EVERY
2 GRANT APPLICATION. SO IF THAT REVIEWER OR HIS
3 IMMEDIATE JUNIOR ASSOCIATE WERE TO TRY AND PUBLISH A
4 PAPER ON THAT, IT WOULD BE AN EXTRAORDINARY PROBLEM
5 FOR THEM IN THEIR INSTITUTION. THEY MIGHT LOSE
6 THEIR POSITION. AND IT WOULD BE AN EXTRAORDINARY
7 PROBLEM FOR THEM IN THE SCIENTIFIC WORLD BECAUSE
8 THEY WOULD HAVE VIOLATED THE CONFIDENTIALITY
9 PROVISIONS. AND SO WE HAVE ACCOUNTABILITY. WE HAVE
10 THE ABILITY TO SEE WHETHER THE PROPRIETARY
11 INFORMATION THAT WAS REVIEWED IN THE GRANT HAS BEEN
12 PICKED UP BY SOMEONE AND LATER TRIED TO BE
13 EXPLOITED.

14 DR. LIPSON: THANK YOU.

15 MR. KLEIN: THANK YOU, SIR.

16 CHAIRMAN CHIANG: OTHER QUESTIONS FROM THE
17 MEMBERS? LET ME ASK A COUPLE OF QUESTIONS.

18 CAN YOU PROVIDE ME WITH A SENSE OF THE
19 STAFFING LEVEL THAT WILL REVIEW THE GRANT REPORTS
20 AND HOW THAT WOULD BE COMMUNICATED TO MANAGEMENT AND
21 THE BOARD?

22 MS. PACHTER: I'M SORRY. COULD YOU REPEAT
23 THE QUESTION?

24 CHAIRMAN CHIANG: THE STAFFING LEVELS.

25 MS. PACHTER: THE STAFFING LEVELS AT CIRM

BARRISTERS' REPORTING SERVICE

1 THAT ARE DEVOTED TO REVIEWING PROGRESS REPORTS?
2 PROGRESS REPORTS ARE REVIEWED ON THE FINANCIAL SIDE
3 AND ON THE SCIENTIFIC SIDE. AND CURRENTLY WE HAVE
4 FOUR MEMBERS OF OUR GRANTS MANAGEMENT OFFICE THAT
5 ARE IN CHARGE OF REVIEWING THE FINANCIAL SIDE
6 ANNUALLY, AND WE HAVE -- ALL OUR SCIENCE OFFICERS
7 SERVE IN DUAL ROLES. SO THEY SERVE TO PUT TOGETHER
8 THE GRANT REVIEW PROGRAMS, AND THEN THEY SERVE AS
9 SCIENTIFIC PROGRAM OFFICERS. AND I THINK WE'RE NOW
10 UP TO 15 SCIENTIFIC OFFICERS, 15, ON THE
11 PROGRAMMATIC SIDE.

12 CHAIRMAN CHIANG: AND THEN HOW MANY OF THE
13 RECOMMENDATIONS BY THE WORKING GROUP HAVE BEEN
14 ACCEPTED BY THE ICOC?

15 MR. KLEIN: TWO THINGS. ONE, OF COURSE,
16 THE COURT'S REVIEWED THIS AND FOUND THAT THERE
17 WASN'T A SYSTEMATIC PATTERN. BOTH THE TRIAL COURT
18 AND COURT OF APPEAL FOUND THAT THE ICOC WAS
19 SELECTIVELY TAKING THESE RECOMMENDATIONS AND MAKING
20 APPROVALS. THERE IS, HOWEVER, A FAIRLY HIGH
21 PERCENTAGE THAT ARE GENERALLY ACCEPTED. IT CAN BE
22 IN THE 90 PERCENT RANGE SOMETIMES. THERE ARE SOME
23 WHERE IT GETS DOWN TO 70 PERCENT BEING WHAT'S CALLED
24 TIER 1 RECOMMENDATIONS FOR FUNDING, AND THE BOARD
25 WILL GO INTO A LOWER GROUP OF RECOMMENDATIONS AND

BARRISTERS' REPORTING SERVICE

1 FOR PROGRAMMATIC REASONS OR FOR REASONS THAT THEY
2 BELIEVE THERE'S BREAKING NEW DEVELOPMENTS OR FOR
3 OTHER SUBSTANTIVE REASONS, THEY WILL APPROVE A
4 SIGNIFICANT SHARE OF THOSE IN ANOTHER CATEGORY.

5 SECONDLY, THE BOARD HAS AT TIMES CHANGED
6 THE AMOUNT OF THE DOLLAR AMOUNT OF RECOMMENDATIONS
7 FROM THE PEER REVIEW COMMITTEE, CHANGED THEM, IN
8 FACT, SIGNIFICANTLY. AND SO BOTH THERE'S A QUESTION
9 IS IT APPROVED AND WHAT DOLLAR AMOUNT IS APPROVED?
10 AND THOSE CHANGES HAVE BEEN MADE AND/OR SOMETIMES
11 INDIVIDUALLY MADE, BUT SOMETIMES MADE FOR A LARGER
12 GROUP.

13 SO I CAN GIVE YOU A MORE DETAILED ANSWER,
14 BUT I'D HAVE TO, TO BE ACCURATE, GO BACK AND DO A
15 RESEARCH OF EVERY ONE OF THE ROUNDS BECAUSE EACH
16 ROUND IS DIFFERENT. WE'RE TRYING TO JUDGE EACH
17 ROUND BASED ON ITS FACTS.

18 CHAIRMAN CHIANG: YEAH. I WAS JUST TRYING
19 TO GET A SENSE SINCE WE'VE HAD QUESTIONING ALONG
20 THIS LINE SLIGHTLY LAST YEAR, SO I WAS JUST TRYING
21 TO SEE WHAT HAS HAPPENED.

22 MR. KLEIN: BUT I WOULD SAY WE'RE
23 BASICALLY -- THERE'S BEEN SOMEWHAT MORE BOARD
24 INDEPENDENCE IN DECISIONS SINCE THE COURT DECISION,
25 AND THE COURT LOOKED SPECIFICALLY AT THIS ISSUE

BARRISTERS' REPORTING SERVICE

1 BECAUSE IF THE BOARD WERE MERELY RUBBER STAMPING THE
2 PEER REVIEW, OF COURSE, WE WOULDN' T NEED AS MANY
3 MEETINGS. WE' VE HAD 120 MEETINGS, I THINK. BUT, IN
4 FACT, THE COURT, BOTH TRIAL COURT OF APPEALS AND
5 STATE SUPREME COURT, FOUND A SIGNIFICANT DEGREE OF
6 INDEPENDENCE, AND THAT THESE GRANT APPLICATIONS WERE
7 BEING TREATED INDIVIDUALLY.

8 WE HAVE A SIGNIFICANT NUMBER OF VOTES
9 WHERE THERE ARE SOME VERY CLOSE VOTES. IT CAN BE,
10 YOU KNOW, 14 TO 12 OR 10 TO 9. I MEAN WE HAVE A
11 SIGNIFICANT NUMBER OF VOTES AT THE MARGIN THAT
12 BECOME PRETTY CLOSE VOTES. SO INDIVIDUAL BOARD
13 MEMBERS ARE ACTING AS INDIVIDUALS AND TRYING TO
14 EVALUATE EVERYTHING THAT THEY' RE RECEIVING, BOTH
15 FROM PUBLIC COMMENT AS WELL AS FROM THE INDIVIDUAL
16 REPORTS FROM PEER REVIEW AND THE APPLICATIONS.

17 DR. LIPSON: I THINK I' M UNDERSTANDING
18 THAT THE BOARD WILL OVERRIDE PEER REVIEW WHEN IT' S
19 QUESTIONABLE SCIENCE IN SOME INSTANCES. IS THAT
20 WHAT YOU' RE SAYING? BECAUSE TO BE ACCEPTED AT THE
21 90TH PLUS PERCENTILE IS STANDARD FOR THE NIH. TO GO
22 DOWN TO 70 IS UNHEARD OF TO FUND SOMETHING LIKE
23 THIS.

24 MR. KLEIN: WELL, A COUPLE OF THINGS. ONE
25 IS IN 1985 THERE WAS ENOUGH FUNDS AT THE NATIONAL

BARRISTERS' REPORTING SERVICE

1 INSTITUTES OF HEALTH THAT THEY WERE FUNDING ABOUT 33
2 PERCENT OF ALL GRANTS. THIS YEAR THE NIH, BECAUSE
3 OF LACK OF FUNDING, WILL FUND ABOUT 4 PERCENT OF ALL
4 RESEARCH. HOPEFULLY RESEARCH IN THIS COUNTRY HAS
5 NOT RADICALLY CHANGED IN TERMS OF ITS QUALITY. WE
6 BELIEVE THERE'S A LOT OF GREAT RESEARCH THAT JUST
7 ISN'T GETTING FUNDED FOR LACK OF FUNDS.

8 BUT THE BOARD MAY DECIDE THAT THE RESEARCH
9 OPPORTUNITIES STRATEGICALLY ARE SO IMPORTANT IN A
10 SPECIFIC AREA THAT THEY'RE GOING TO FUND MORE GRANTS
11 THAN THE GRANTS RECOMMENDED BY THE PEER REVIEW GROUP
12 FOR FUNDING BECAUSE OF THE QUALITY OF IT.

13 NOW, REALIZE, THE BOARD, AND ONLY THOSE
14 WHO ARE NOT INVOLVED IN THE GRANT CAN VOTE, HAS
15 SEVEN MEDICAL SCHOOL DEANS, INCLUDING ALL THE UC
16 MEDICAL SCHOOL DEANS, STANFORD AND USC, CHANCELLOR
17 OF UC BERKELEY, IT HAS THE PRESIDENT OF THE SALK
18 INSTITUTE, PRESIDENT OF THE BURNHAM INSTITUTE,
19 PRESIDENT OF THE CITY OF HOPE, WHO'S A FORMER FDA
20 COMMISSIONER, PLUS PATIENT ADVOCATES WHO REALLY WANT
21 TO SEE ONLY THE BEST SCIENCE FUNDED.

22 I WILL TELL YOU AT OUR LAST GRANT ROUND,
23 WE ACTUALLY FUNDED LESS GRANTS THAN OUR BUDGET FOR
24 THE GRANT ROUND. SO THAT WAS A PARTICULAR GRANT
25 ROUND WE DIDN'T THINK THE SCIENCE WAS COMPLETELY

BARRISTERS' REPORTING SERVICE

1 THERE, AND WE FUNDED LESS THAN WE HAD TOLD
2 APPLICANTS WAS AVAILABLE FOR FUNDING WHEN THE
3 APPLICANTS SUBMITTED THEIR APPLICATIONS.

4 DR. LIPSON: I UNDERSTAND. BUT, AGAIN, IF
5 YOU'RE USING WORLD FAMOUS, PRESTIGIOUS 15 PEOPLE WHO
6 ARE IMPECCABLE, AND THEY SAY SOMETHING IS
7 QUESTIONABLE, OVERRIDING THAT IS SOMETHING THAT
8 NEEDS TO BE THOUGHT ABOUT.

9 MR. KLEIN: IT IS NOT THAT THEY SAID THEY
10 TAKE A POSITION. WELL, THE POSITIONS ARE HIGHLY
11 ARTICULATED REVIEWS. AND THOSE ARE READ BY THE
12 SCIENCE STAFF, AND THOSE REVIEWS HAVE VERY
13 SIGNIFICANTLY ARTICULATED ACUTELY FOCUSED
14 STATEMENTS. SO IF THERE ARE THREE AIMS TO THE
15 RESEARCH, THE REVIEW MAY SAY THAT AIM 1 AND 2 ARE
16 EXCELLENT, AIM 3 IS JUST CONFUSED AND OFF THE MARK
17 AND NOT GOING TO HAPPEN. THE BOARD MAY FEEL THAT
18 AIM 1 AND 2 ARE CRITICAL LEAD ITEMS TO RESEARCH
19 WE'RE DOING, AND THAT WE REALLY NEED THIS FOR THE
20 PROGRAM TO ADVANCE.

21 THE FACT THAT AIM 3 MAY NOT BE
22 ACCOMPLISHED GOES BACK TO THE RESEARCHER WITH
23 CRITICAL COMMENTS ON HOW TO MAKE IT POSSIBLE TO
24 ACCOMPLISH IT, OR INSTRUCTS THEM TO REALLY FOCUS ON
25 AIM 1 AND 2. SO WE'RE ACUTELY DEALING WITH THESE AS

BARRISTERS' REPORTING SERVICE

1 VERSUS A DICHOTOMOUS UP-OR-DOWN DECISION.

2 DR. LIPSON: I HEAR WHAT YOU ARE SAYING.

3 MR. KLEIN: THANK YOU, SIR.

4 CHAIRMAN CHIANG: ANY OTHER QUESTIONS?

5 PUBLIC COMMENT? OKAY.

6 NEXT ITEM, UPDATE ABOUT CIRM'S FINANCIAL
7 PERFORMANCE, UPDATES OF GRANTS AWARDED AND GRANT
8 PROCESS.

9 MR. KLEIN: MR. CHAIRMAN AND MEMBERS OF
10 THE OVERSIGHT COMMITTEE, IT'S A PRIVILEGE TO ADDRESS
11 YOU TODAY. I WANT TO, PARTICULARLY IN REVIEWING
12 MAJOR ACTIONS TO DATE, THANK THE CONTROLLER AND HIS
13 STAFF FOR THE CONTROLLER'S AUDIT THAT WAS JUST
14 COMPLETED.

15 THE CONTROLLER'S OFFICE HAD AT TIMES SEVEN
16 PEOPLE ASSIGNED TO THE JOB, SO WE FEEL THOROUGHLY
17 REVIEWED. THEY KNOW EVERYTHING ABOUT US THAT WE
18 KNOW, BUT IT IS A VERY IMPORTANT PROCESS BECAUSE IT
19 GIVES CONFIDENCE TO THE PUBLIC, CONFIDENCE THAT
20 THEY'VE LOOKED UNDER EVERY BOOK, UNDER EVERY
21 DOCUMENT. AND THIS COMPLETES THE THIRD BRANCH OF
22 STATE GOVERNMENT'S REVIEW.

23 WE HAVE, AS HAS BEEN REFERENCED HERE
24 TODAY, BEEN REVIEWED IN DETAIL BY THE COURT SYSTEM
25 FOR WHICH WE SUBMITTED 20,000 PAGES OF DOCUMENTATION

BARRISTERS' REPORTING SERVICE

1 AND THE OPPOSITION SUBMITTED A SIMILAR AMOUNT. WE
2 HAVE BEEN REVIEWED BY THE LEGISLATURE THROUGH THE
3 BSA AUDIT THAT HAS BEEN REVIEWED HERE IN DETAIL, AND
4 WE LEARNED FROM THE CONTROLLER'S OFFICE, WE LEARNED
5 FROM THE BSA HOW TO MAKE THIS A BETTER AGENCY FOR
6 THE PUBLIC AND FOR PATIENTS.

7 SO AT THIS POINT WE'VE BEEN REVIEWED BY
8 THE CONTROLLER'S OFFICE REPRESENTING THE EXECUTIVE
9 BRANCH, COMPLETING ALL THREE BRANCHES OF GOVERNMENT,
10 AND ALL THREE BRANCHES FINDING THAT WE ARE IN
11 COMPLIANCE WITH PROPOSITION 71, AND SPECIFICALLY
12 ADDRESSING SOME OF THE QUESTIONS THAT HAVE BEEN
13 ADDRESSED HERE TODAY.

14 EARLIER TODAY THERE WAS AN INDIVIDUAL
15 QUOTING FROM THE COURT OF APPEALS' DECISION ABOUT
16 THE VALUE OF AN EXPERT COMMITTEE OUTWEIGHING THE
17 RISK OF CONFLICTS SPECIFICALLY WHEN THE DECISIONS
18 CANNOT BE INFLUENCED BY PEOPLE WITH PERSONAL OR
19 PROFESSIONAL INTEREST IN THOSE DECISIONS. I'D LIKE
20 TO POINT OUT THAT THAT COURT OF APPEALS' DECISION
21 WENT FURTHER AND SAID, IN CITING ANOTHER CASE, THAT
22 IT WAS CONFIRMING AND CONFIRMED LATER BY THE STATE
23 SUPREME COURT THAT THIS COURT UPHELD THE VALIDITY OF
24 A REGULATION PERMITTING INDUSTRY MEMBERS TO SERVE ON
25 A BOARD REGULATING ANOTHER INDUSTRY AS LONG AS THEY

BARRISTERS' REPORTING SERVICE

1 DID NOT PARTICIPATE IN THOSE DECISIONS. AND THAT
2 THE COURT POINTED TO A SURVEY BY THE FAIR POLITICAL
3 PRACTICES COMMISSION INDICATING THAT IN CALIFORNIA
4 THERE ARE APPROXIMATELY 92 STATE BOARDS, AS WELL AS
5 NUMEROUS LOCAL BOARDS, WHICH INCLUDE SUCH MEMBERS.

6 SO OUR USE OF AN EXPERT BOARD, INDIVIDUALS
7 THAT HAVE KNOWLEDGE SPECIFICALLY IN THE INDUSTRY, IS
8 SOMETHING THAT IS LONG PRACTICED IN CALIFORNIA TO
9 GET THE KNOWLEDGE NECESSARY TO MAKE CRITICAL,
10 DISCRIMINATING DECISIONS. AND AS MR. LIPSON POINTS
11 OUT, SOMETIMES THOSE DECISIONS HAVE TO BE VERY TOUGH
12 DECISIONS.

13 I WOULD ALSO POINT OUT THAT AT THE END OF
14 THE OPINION, THE COURT CONCLUDED BY SAYING, "AFTER
15 CONSIDERATION OF ALL OF APPELLANT'S LEGAL
16 OBJECTIONS, WE HAVE NO HESITATION IN CONCLUDING IN
17 THE EXERCISE OF OUR SOLEMN DUTY TO JEALOUSLY GUARD
18 THE PRECIOUS INITIATIVE POWER, THAT PROPOSITION 71
19 SUFFERS NO LEGAL INFIRMITY AND IS BEING ADMINISTERED
20 CONSISTENT WITH THE INITIATIVE."

21 I WOULD LIKE TO GO AT THIS POINT TO
22 FINANCIAL PERFORMANCE, PROGRAM PERFORMANCE, AND A
23 REVIEW OF OUR IP REGULATIONS WHICH GO TO THE HEART
24 OF THE SOME OF THE QUESTIONS HERE TODAY.

25 IF WE COULD BRING UP A SLIDE THAT WE HAVE

BARRISTERS' REPORTING SERVICE

1 ON OUR GRANT APPROVALS. I WANT THE SLIDE THAT SHOWS
2 THE DISTRIBUTION OF GRANTS. IT'S IN A DIFFERENT
3 FILE, SO I'LL GO ON TO THE NEXT SLIDE. CAN YOU GO
4 TO THE MAJOR FACILITIES SLIDE, PLEASE?

5 CHAIRMAN CHIANG: BOB, WAS THAT SUBMITTED
6 IN THE PACKET YOU GAVE?

7 MR. KLEIN: YOU HAVE A COPY OF IT, YES.
8 IT SHOULD BE A BLUE CHART AND IT SHOULD LOOK LIKE
9 THIS. IT'S ACTUALLY -- IN YOUR MATERIALS IT'S
10 BLACK.

11 CHAIRMAN CHIANG: GOT IT. I THOUGHT YOU
12 WERE REFERENCING RECENT MATERIAL SUBMITTED.

13 MR. KLEIN: ALL RIGHT. SO THE POSITIVE
14 NEWS FROM THE AGENCY IS THAT IN THE YEAR SINCE THE
15 COURT GAVE US THE FINAL APPROVAL FOR THE
16 CONSTITUTIONALITY OF OUR LEGISLATION AND AFFIRMING
17 THE AGENCY'S ACTIONS AND AUTHORITY, REJECTING 54
18 DIFFERENT CLAIMS BY THE OPPOSITION CHALLENGING EVERY
19 PART OF OUR OPERATIONS, WE HAVE MOVED FORWARD WITH A
20 PROGRAM THAT WAS IN PROGRESS AT THAT TIME, BUT WE
21 HAVE CONSUMMATED \$560 MILLION IN GRANTS.
22 APPROXIMATELY \$290 MILLION OF THOSE ARE DISTRIBUTED
23 TO 26, I BELIEVE, INSTITUTIONS, AND WE'LL BRING UP
24 THAT CHART LATER, WHICH IS PART OF YOUR MATERIALS
25 THAT YOU'VE DISTRIBUTED.

BARRISTERS' REPORTING SERVICE

1 BUT I'D LIKE TO FOCUS FOR A MOMENT ON
2 MAJOR FACILITIES BECAUSE IT ADDRESSES A NUMBER OF
3 POINTS WHERE QUESTIONS WERE RAISED EARLIER TODAY.
4 AS YOU CAN SEE FROM THE LEFT-HAND COLUMN, WHICH
5 HOPEFULLY YOU CAN READ BETTER ON THE MATERIALS
6 BEFORE YOU, THE INSTITUTIONS WHO ARE LISTED ON THE
7 FAR LEFT-HAND COLUMN, AND THEY GO FROM STANFORD TO
8 THE SAN DIEGO CONSORTIUM TO UC SAN FRANCISCO DOWN TO
9 USC, UC DAVIS, ETC., THE FIRST SEVEN INSTITUTIONS
10 ARE WHAT'S CALLED INSTITUTES.

11 THEY HAD TO GO THROUGH SCIENTIFIC PEER
12 REVIEW FOR BASIC RESEARCH, APPLIED RESEARCH, AND
13 CLINICAL RESEARCH, AND BE GRADED ON ALL THREE. THE
14 NEXT TWO ARE WHAT'S CALLED CENTERS OF EXCELLENCE,
15 AND THOSE HAD TO COMPETE IN SCIENTIFIC REVIEW WITH
16 BASIC AND APPLIED RESEARCH. UC BERKELEY, FOR
17 EXAMPLE, DOESN'T HAVE A MEDICAL SCHOOL, SO IT COULD
18 NOT COMPETE IN THE INSTITUTE CATEGORY. AND THEN THE
19 LAST THREE ARE UC INSTITUTIONS WHERE THERE IS A
20 SPECIFIC EXCELLENCE THAT, FOR EXAMPLE, UC SANTA CRUZ
21 IS KNOWN FOR ITS SYSTEM BIOLOGY APPROACH, IN WHICH
22 IT DOES A NUMBER OF COLLABORATIONS WITH STANFORD AND
23 WAS SUPPORTED IN ITS APPLICATION BY DOCUMENTATION
24 FROM STANFORD ON THE WORLD-CLASS QUALITY OF THEIR
25 RESEARCH WITH CITATIONS.

BARRISTERS' REPORTING SERVICE

1 WHEN YOU LOOK AT THESE INSTITUTIONS,
2 THERE' S \$832 MILLION IN APPLICATIONS. NOW, REALIZE
3 THERE' S 17 INSTITUTIONS THAT APPLIED. OUR
4 SCIENTIFIC REVIEW COMPLETELY ELIMINATED FIVE
5 INSTITUTIONS. SO THESE ARE THE ONLY 12 THAT GOT
6 THROUGH SCIENTIFIC REVIEW. NOW, THEY APPLIED FOR
7 \$832 MILLION. AS STEWARDS OF THE PUBLIC AND AS
8 ACUTELY AWARE THAT WE HAVE LIMITED RESOURCES, IN OUR
9 PUBLIC HEARINGS ON THE FACILITIES COMMITTEE, WE SET
10 CRITERIA REQUIRING LEVERAGE, FINANCIAL LEVERAGE, AS
11 ONE OF THE CRITERIA UNDER WHICH WE WOULD AWARD
12 FUNDS. SO YOU HAVE TO FIRST MEET THE SCIENTIFIC
13 QUALITY, THEN HAVE YOU TO MEET YOUR FUNCTIONAL
14 QUALITY, YOU HAVE TO GET AN EVALUATION ON YOUR
15 FACILITY' S COST-EFFECTIVENESS, AND YOU HAVE TO MEET
16 LEVERAGE REQUIREMENTS.

17 SO OUR \$271 MILLION APPROXIMATELY WE WERE
18 ABLE TO GAIN, NOT ONLY \$561 MILLION IN DONOR AND
19 INSTITUTIONAL COMMITMENTS IN MATCHING FUNDS, BUT
20 ANOTHER \$322 MILLION IN PLEDGES FOR FACULTY HIRING
21 AND START-UP COSTS, INCLUDING EQUIPMENT
22 ACQUISITIONS. SO THAT FOR OUR \$270 MILLION, WE WERE
23 ABLE TO OBTAIN \$1,155,000,000 FOR THE PATIENTS OF
24 THIS STATE. HOPEFULLY THAT IS AN EXTRAORDINARY
25 EXAMPLE OF A COMMITMENT TO FURTHERING MEDICAL

BARRISTERS' REPORTING SERVICE

1 RESEARCH AND FURTHERING THE RESOURCES, HANDLING THEM
2 WITH EXTREME CARE TO GET THE MOST POSSIBLE FOR THE
3 PUBLIC AND FOR PATIENTS IN CALIFORNIA WITH A GENERAL
4 BENEFIT TO PATIENTS IN THE WORLD.

5 THAT, AS YOU CAN SEE, WILL CREATE 784,000
6 SQUARE FEET OF SPACE. IN ADDITION, THERE'S 2,200
7 SCIENTISTS AND CLINICIANS THAT WORK IN THAT SPACE.
8 THAT EXCLUDES JANITORS, THAT EXCLUDES THE
9 ADMINISTRATIVE PERSONNEL. AND WHAT YOU FIND AS WELL
10 IS THERE ARE A COUPLE OF THOSE INSTITUTIONS THAT
11 HAVE STARS ON THEM. FOR EXAMPLE, UCLA IN THE RIGHT
12 COLUMN, THERE'S 114 SCIENTISTS THERE. THAT FACILITY
13 WILL BE RETAINED IN ADDITION TO THE NEW FACILITY
14 THAT THEY'RE ADDING. THAT'S ALSO TRUE ON UC SAN
15 FRANCISCO, ALTHOUGH I DON'T THINK WE HAVE A STAR ON
16 THAT COLUMN.

17 NOW, THESE RESOURCES COME TO THE STATE OF
18 CALIFORNIA IN ADDITION TO THE RESOURCES OF RECENTLY
19 BUILT FACILITIES LIKE THE GLADSTONE INSTITUTE, WHICH
20 HAD ALREADY BUILT ITS NEW FACILITY, SO IT COULD NOT
21 COME IN AND COMPETE.

22 THERE ARE OTHER INSTITUTIONS THAT WERE NOT
23 READY TO MEET OUR REQUIREMENTS. OUR REQUIREMENTS
24 WERE THEY HAVE TO BUILD THESE, HAVE THEM FULLY
25 OPERATIONAL, AND STAFFED IN 24 MONTHS FROM THE TIME

BARRISTERS' REPORTING SERVICE

1 WE PROVIDE OUR FUNDS. SO THEY KNEW ABOUT THE
2 APPLICATION DECISION IN MAY, BUT THE FUNDS CAME
3 ACROSS IN JUNE, JUST ABOUT THREE WEEKS AGO. AND
4 MANY OF THE INSTITUTIONS WERE IN CONSTRUCTION
5 ALREADY AT THAT TIME BECAUSE THEY COULDN'T WAIT FOR
6 THE FUNDS TO START CONSTRUCTION AND MEET THE
7 REQUIREMENT THAT THEY BE OPERATIONAL IN 24 MONTHS.
8 USUALLY THESE FACILITIES TAKE FOUR OR FIVE YEARS TO
9 BUILD, AND THESE INSTITUTIONS HAVE ALL FAST TRACKED
10 THESE, KNOWING THAT TO COMPETE, THEY HAD TO MEET
11 THIS REQUIREMENT.

12 THERE'S AN EXCEPTION TO THAT IN THAT UC
13 SANTA CRUZ, WHICH GOT A SMALL AWARD, WAS IN A
14 POSITION THAT BECAUSE OF COASTAL ZONE APPROVAL, THEY
15 COULD NOT MEET THAT 24 MONTHS, AND THEY WERE
16 SPECIFICALLY APPROVED FOR FIVE MILLION, A VERY SMALL
17 SHARE OF THE FUNDS. THEY COULDN'T HAVE COMPETED FOR
18 A LARGE SHARE OF THE FUNDS BECAUSE THEY COULDN'T
19 MEET THAT URGENCY REQUIREMENT.

20 WHAT WE HAVE FOUND FROM THIS IS NOT ONLY
21 ARE WE CONTRIBUTING TREMENDOUSLY TO THE CAPACITY OF
22 THE STATE IN STEM CELL RESEARCH, BUT -- YOU HAVE THE
23 SLIDE THERE ON THE FINANCIAL ANALYSIS? THIS SLIDE
24 ON FINANCIAL ANALYSIS, WE JUST RECEIVED THIS REPORT
25 OVER THE 4TH OF JULY WEEKEND, AND YOU DON'T HAVE

BARRISTERS' REPORTING SERVICE

1 THIS AT THIS POINT. WE WILL GIVE IT TO THE --
2 CONVEY IT TO THE CONTROLLER'S OFFICE SO THAT THE
3 CONTROLLER'S OFFICE CAN SEND IT OUT.

4 JUST TO SUMMARIZE FOR YOU, THIS WAS AN
5 ECONOMIC ANALYSIS DONE BY AN ECONOMIST AT STANFORD
6 UNIVERSITY SCHOOL OF MEDICINE ALONG WITH AN ANALYSIS
7 GROUP, WHICH IS AN OUTSIDE PRIVATE FIRM THAT DOES
8 COST-BENEFIT STUDIES FOR HEALTHCARE INSTITUTIONS.
9 AND IN THE LOWEST BOX THAT YOU FIND THERE, YOU WILL
10 SEE THAT WHAT HAPPENED, AND THEY'RE COMPARING THESE
11 TO WHAT THE ORIGINAL PROJECTIONS WERE THAT WERE
12 REVIEWED BY THE LEGISLATIVE ANALYST AT THE TIME OF
13 THE INITIATIVE ITSELF, AND THEY'RE SHOWING THAT
14 DONOR AND INSTITUTIONAL MATCHING FUNDS AS A
15 PERCENTAGE OF CIRM SPENDING WERE 281 PERCENT HIGHER
16 THAN PROJECTED IN THE INITIAL STUDIES THAT WERE DONE
17 AT THE TIME OF THE INITIATIVE AND SUBMITTED TO THE
18 LEGISLATIVE ANALYST'S OFFICE.

19 A RARE CASE WHERE YOU FIND AN INITIATIVE
20 THAT IS OVERPERFORMING, SUBSTANTIALLY OVERPERFORMING
21 ON WHAT HAS BEEN PROMISED. AND HOPEFULLY GOOD NEWS
22 TO THE STATE CONTROLLER, WHO IS CAREFUL WITH ALL OF
23 OUR STATE FUNDS. IT SHOWS THAT TAX REVENUES TO
24 CALIFORNIA ARE EXPECTED, JUST FROM THIS ONE PROGRAM,
25 TO BE \$99.1 MILLION, WHICH IS 277 PERCENT HIGHER

BARRISTERS' REPORTING SERVICE

1 THAN WHAT WAS EXPECTED FROM THE MAJOR FACILITIES
2 CONSTRUCTION PROGRAM AT THE TIME THAT THE INITIATIVE
3 WAS LAUNCHED.

4 ADDITIONALLY, THERE ARE 13,272
5 CONSTRUCTION JOBS TO BE CREATED, WHICH IS 239
6 PERCENT HIGHER THAN THE INITIAL PROJECTIONS,
7 VALIDATING THOSE PROJECTIONS. BUT PERHAPS MORE
8 IMPORTANTLY WHAT IT VALIDATES IS THAT WHEN YOU CAN
9 SHOW MAJOR INSTITUTIONS AND MAJOR DONORS THAT YOU
10 CAN PROVIDE LONG-TERM STABILITY, SO STRATEGIC
11 SCIENTIFIC DECISIONS CAN BE MADE, NOT SCIENTIFIC
12 DECISIONS THAT DEPEND UPON EVERY YEAR'S BUDGET WHERE
13 THE BUDGET MAY BE UP ONE YEAR BECAUSE YOU'VE GOT
14 TREMENDOUS AMOUNT OF CAPITAL GAINS TAX AND DOWN THE
15 NEXT YEAR, AS IS CALIFORNIA'S HISTORY. WHEN YOU CAN
16 SHOW A LONG-TERM STABILITY, YOU HAVE THIS TREMENDOUS
17 OUTPOURING FROM THE CIVIC SOCIETY ENDORSING AND
18 VALIDATING THE IMPORTANCE OF STRATEGIC FUNDING FOR
19 SCIENCE AND MEDICINE.

20 WE SHOULD RECALL THAT IT IS ONLY ABOUT
21 SEVEN YEARS AGO WHERE STANFORD WAS OFFERED BY
22 MR. CLARK \$60 MILLION TO INVEST IN WHAT'S CALLED THE
23 BUILDING X WHERE HE WANTED A PORTION OF THAT
24 BUILDING TO BE A STEM CELL RESEARCH CENTER.
25 STANFORD GAVE BACK THE 60 MILLION BECAUSE STANFORD

BARRISTERS' REPORTING SERVICE

1 SAID THERE WAS NO LONG-TERM, STABLE, PREDICTABLE
2 FUNDING SOURCE TO SUPPORT OPERATIONS IF YOU BUILT
3 IT. SO HERE'S THE SAME INSTITUTION THAT GAVE BACK
4 \$60 MILLION. THEY ARE NOW PUTTING UP ON THEIR OWN
5 ABOUT \$180 MILLION OF FUNDS IN ORDER TO PARTICIPATE
6 IN WHAT THEY FEEL IS A STRATEGIC OPPORTUNITY.

7 DR. LIPSON: MR. KLEIN, QUESTION ABOUT
8 SOME OF THE FUND AMOUNTS. THE CIRM GROUP HAS
9 AWARDED \$270,946,000, ETC., AND DONOR INSTITUTIONS
10 HAVE SUPPOSEDLY COME UP WITH OVER HALF A BILLION
11 DOLLARS OF PROJECT FUNDS. IS THAT TRULY NEW MONEY
12 OR MONEY ALREADY IN THE VARIOUS AREAS THAT THEY JUST
13 PUT TOGETHER TO SHOW THEY'RE DOING IN-KIND TYPE OF
14 RESEARCH? MY EXPERIENCE IS TO RAISE THAT AMOUNT OF
15 MONEY IS VERY UNLIKELY TAKING INTO ACCOUNT THINGS
16 THAT ARE ALREADY ONGOING.

17 MR. KLEIN: OKAY. FIRST OF ALL, THIS IS
18 JUST FOR THE MAJOR FACILITIES PROGRAM. SO IT'S
19 OUTSIDE THE \$290 MILLION WE'VE APPROVED IN GRANTS.
20 SO THESE ARE NEW BUILDINGS. THESE ARE BUILDINGS
21 THAT WERE NOT ON THE DRAWING BOARDS, THAT SINCE
22 PROPOSITION 71, THEY'VE RAISED TO MEET OUR
23 REQUIREMENTS TO DESIGN AND BUILD NEW FACILITIES.

24 IN THE CASE OF UC DAVIS, THEY MOVED
25 FORWARD AND BOUGHT A BUILDING THAT THEY ARE

BARRISTERS' REPORTING SERVICE

1 REHABBING, COMPLETELY REHABBING, BUT THESE ARE NEW
2 FUNDS. THEY'RE SUBJECT TO AUDIT OF THESE FUNDS; AND
3 IF UNDER THE AUDIT, THEY HAVE NOT EXPENDED THE FUNDS
4 THAT WERE PLEDGED, LESS ANY DISCOUNTS THAT THEY'VE
5 ALREADY GIVEN US, THEY HAVE TO GIVE US BACK A
6 PROPORTIONAL REDUCTION IN THE FUNDS WE'VE PUT UP.

7 DR. LIPSON: IT'S, AGAIN, HARD TO BELIEVE
8 THAT ALL THIS IS BRAND NEW.

9 MR. KLEIN: WELL, I'VE ACTUALLY, SIR,
10 TALKED TO A NUMBER OF THE MAJOR DONORS AND TALKED TO
11 THEM IN-DEPTH AS THEY WERE MAKING THEIR DECISIONS
12 ABOUT CONTRIBUTIONS. AND THE DONORS' PERCEPTION IS
13 THAT THEY WERE NOT PREPARED PREVIOUSLY TO MAKE THIS
14 KIND OF CONTRIBUTION AND MADE IT SPECIFICALLY IN
15 RESPONSE TO PROPOSITION 71 AND THIS SPECIFIC
16 OPPORTUNITY TO MARSHAL THE PHYSICAL ASSETS TO DO
17 THIS WORLD-CLASS RESEARCH.

18 DR. LIPSON: AND THE SAME QUESTION ABOUT
19 THE \$322,500,000.

20 MR. KLEIN: YES, SIR.

21 DR. LIPSON: AGAIN, IS THAT NEW OR IS THAT
22 ONGOING EFFORTS IN VARIOUS BIOCHEMISTRY AREAS AND
23 MOLECULAR BIOLOGY AREAS WHICH DOVETAIL IN SOME WAY
24 WITH THE STEM CELL RESEARCH?

25 MR. KLEIN: WELL, THIS SPECIFICALLY TO BE

BARRISTERS' REPORTING SERVICE

1 COUNTED HAS TO BE FOR SCIENTISTS AND CLINICIANS
2 MOVING INTO THESE NEW FACILITIES. IF YOU LOOK AT
3 THE SCALE OF THE INCREASE IN THE NUMBER OF
4 SCIENTISTS FROM 826 TO 2,200, THAT, I EXPECT, WILL
5 TAKE MASSIVELY MORE MONEY THAN THEY'RE EVEN CLAIMING
6 CREDIT FOR RIGHT NOW BECAUSE THE ONLY THING THE 322
7 REPRESENTS IS THE INITIAL HIRING BONUSES AND
8 EQUIPMENT, OR INITIAL RECRUITMENT COST AND
9 EQUIPMENT.

10 DR. LIPSON: THANK YOU.

11 MR. KLEIN: YES, SIR.

12 I WOULD LIKE TO INDICATE THAT YOU HAVE IN
13 YOUR CHARTS A DISTRIBUTION OF THE VARIOUS GRANT
14 PROGRAMS THAT SHOW THE DISTRIBUTION OF THE \$290
15 MILLION IN THE TRAINING GRANTS, THE SEED GRANTS, THE
16 COMPREHENSIVE GRANTS, THE SHARED LAB GRANTS, THE NEW
17 FACULTY GRANTS IN ADDITION TO WHAT WE'VE DISCUSSED
18 HERE. BUT IN TRYING TO OBSERVE THE TIME THAT WE
19 HAVE HERE, I'VE HIGHLIGHTED THE PARTICULAR PROGRAM.

20 I WOULD LIKE AT THIS POINT TO ASK THAT
21 DR. ED PENHOET COME FORWARD AND DESCRIBE FOR YOU THE
22 INTELLECTUAL PROPERTY PROGRAM THAT WE'VE PUT IN
23 PLACE TO TRY AND ASSURE THAT THE GOALS OF THE
24 CONTROLLER'S OFFICE, THE GOALS OF THE PUBLIC, AND
25 THE GOALS OF PROP 71 ARE MET, BOTH IN CAPTURING SOME

BARRISTERS' REPORTING SERVICE

1 OF THIS BENEFIT FOR CALIFORNIA AND PROTECTING THE
2 INTELLECTUAL PROPERTY THAT MR. LIPSON REFERENCED.
3 THANK YOU.

4 DR. PENHOET: THANK YOU, BOB. CHAIRMAN
5 CHIANG, MEMBERS OF THE COMMITTEE, I'M ED PENHOET.
6 I'M VICE CHAIR OF THE COMMISSION. AND I'VE LED THE
7 INTELLECTUAL PROPERTY POLICY DEVELOPMENT TOGETHER
8 WITH CAPABLE ASSISTANCE OF SCOTT TOCHER HERE TODAY.
9 AS CHAIRMAN KLEIN PREVIOUSLY INDICATED, WE'RE
10 PLEASED THAT WE HAVE NOW COMPLETED BOTH THE
11 NOT-FOR-PROFIT POLICY AND THE FOR-PROFIT POLICY, AND
12 ALL OF THE CONCLUSIONS THAT WE REACHED ARE NOW IN
13 FRONT OF THE OFFICE OF ADMINISTRATIVE LAW, SOON TO
14 BECOME REGULATIONS.

15 THE PROCESS ITSELF HAS BEEN AN EXTENSIVE
16 PROCESS. WE HAVE HAD MORE THAN 15 PUBLIC MEETINGS,
17 18 PROFESSIONAL PRESENTATIONS. MORE THAN 20
18 INSTITUTIONS HAVE BEEN SURVEYED AROUND THE WORLD TO
19 LEARN BEST PRACTICES IN THIS FIELD. WE'VE CONDUCTED
20 IN THAT PROCESS MORE THAN A HUNDRED INTERVIEWS OF
21 PEOPLE IN FOUNDATIONS THAT SUPPORT BIOMEDICAL
22 RESEARCH, A VARIETY OF GOVERNMENTAL AGENCIES, ETC.
23 WE HAVE HAD 12 ROUNDS OF PUBLIC COMMENT ON THE
24 PROPOSED REGULATIONS, AND WE'VE HAD MORE THAN A
25 HUNDRED FORMAL COMMENT LETTERS SUPPLIED TO US. SO

BARRISTERS' REPORTING SERVICE

1 WE HAVE HAD A VERY ROBUST PROGRAM OF SEEKING INPUT
2 FROM A WHOLE VARIETY OF BOTH PROFESSIONAL SOURCES
3 AND THE PUBLIC IN DEVELOPING THE POLICIES THAT WE
4 HAVE IN FRONT OF US.

5 WE REVIEWED FOR YOU LAST YEAR WHERE WE
6 WERE WITH THE NOT-FOR-PROFIT POLICIES. AND I CAN
7 TELL YOU THAT THE POLICIES THAT WE'VE DEVELOPED FOR
8 THE FOR-PROFIT SECTOR LARGELY MIRROR THOSE THAT WERE
9 ARRIVED AT FOR THE NOT-FOR-PROFIT SECTOR. WE HAVE
10 VERY SIMILAR REQUIREMENTS FOR DATA SHARING, WE HAVE
11 VERY SIMILAR REQUIREMENTS FOR MANY OF THE ASPECTS OF
12 PRICING OF PRODUCTS RELATING TO BOTH PRODUCTS THAT
13 WILL BE PURCHASED WITH PUBLIC FUNDS OR PRODUCTS THAT
14 WILL BE SUPPLIED TO INDIVIDUALS WHO ARE NOT
15 QUALIFIED FOR ANY PROGRAM, NEVERTHELESS UNINSURED
16 AND CAN'T AFFORD THOSE PRODUCTS. SO ALL OF THOSE
17 THINGS ARE VERY SIMILAR BETWEEN THE TWO PROGRAMS.

18 WHAT IS DIFFERENT IS THE REVENUE SHARING
19 FEATURES. IN THE CASE OF THE NOT-FOR-PROFIT, AS YOU
20 MAY RECALL, THE DIRECT RETURN TO THE STATE INVOLVES
21 A SHARE OF THE NOT-FOR-PROFIT'S LICENSING REVENUES
22 THAT WOULD BE GIVEN TO THE STATE, IN THAT CASE 25
23 PERCENT OF THOSE REVENUES.

24 IN THE CASE OF THE FOR-PROFIT SECTOR, WE
25 ANTICIPATE AND HOPE THAT MANY OF THESE COMPANIES

BARRISTERS' REPORTING SERVICE

1 WILL, IN FACT, COMMERCIALIZE THESE PRODUCTS
2 THEMSELVES; AND, THEREFORE, WE PUT IN PLACE A
3 PROCESS BY WHICH A SERIES OF PAYMENTS WOULD BE MADE
4 TO THE STATE BASED ON SUCCESSFUL COMMERCIALIZATION
5 OF PRODUCTS THAT WOULD PROVIDE TO THE STATE EITHER
6 THREE TIMES, SIX TIMES, OR NINE TIMES THE STATE'S
7 INVESTMENT IN THE PRODUCT AS A RESULT OF THE
8 SUCCESSFUL COMMERCIALIZATION OF THE PRODUCT. THAT
9 WOULD OBVIOUSLY NOT BE TRUE FOR NOT-FOR-PROFIT
10 BECAUSE THEY'RE NOT IN THE BUSINESS OF SELLING
11 PRODUCTS THEMSELVES.

12 IF, HOWEVER, THE FOR-PROFIT AGENCY
13 BUSINESS DECIDES TO OUT-LICENSE THE PRODUCT RATHER
14 THAN COMMERCIALIZE IT ITSELF, THEN THE RETURN TO THE
15 STATE WOULD BE ESSENTIALLY THE SAME AS IN THE CASE
16 WITH THE NOT-FOR-PROFIT.

17 AS MR. KLEIN INDICATED BEFORE, WE THINK WE
18 HAVE ADDRESSED ALL OF THE MAJOR CONCERNS WHEN IT
19 COMES TO ACCESS. AND I WANT TO EMPHASIZE AGAIN OUR
20 PROGRAM DOES ANTICIPATE A SERIOUS EFFORT TO MAKE
21 SURE THAT ANY PRODUCTS THAT RESULT FROM CIRM-FUNDED
22 RESEARCH ARE AVAILABLE TO CITIZENS OF CALIFORNIA AT
23 THE LOWEST POSSIBLE PRICE WHEN THOSE PRODUCTS ARE
24 PAID FOR WITH PUBLIC FUNDS OF ANY SORT.

25 AND THERE WE HAVE BENCHMARKED OURSELVES

BARRISTERS' REPORTING SERVICE

1 AGAINST THE CALRX PROGRAM WHICH PRESUMABLY SOMEDAY
2 WILL COME INTO BEING AND BENCHMARKED AGAINST THE
3 THREE MAJOR COMPONENTS OF THE CALRX PROGRAM, WHICH
4 ARE EITHER THE LOWEST COMMERCIAL PRICE, THE FEDERAL
5 MEDICAID BEST PRICE, OR 85 PERCENT OF THE AVERAGE
6 MANUFACTURER'S PRICE. SO THESE ARE THE THREE
7 BENCHMARKS THAT ARE EMBODIED IN THE LEGISLATION
8 AROUND CALRX.

9 SO WE DEALT WITH PRICING FOR SITUATIONS IN
10 WHICH GOVERNMENTAL AGENCIES WOULD BE PAYING THE BILL
11 FOR THE SUBSTANCES OR THE TREATMENTS THAT EMERGE
12 FROM OUR PROGRAM. AS BOB INDICATED BEFORE, WE THINK
13 THE BEST WAY TO DEAL WITH THIS ISSUE IS IN
14 REGULATION RATHER THAN IN STATE LAW BECAUSE WE NEED
15 THE FLEXIBILITY TO ANTICIPATE CIRCUMSTANCES IN WHICH
16 THERE MAY BE ORPHAN DISEASES OR OTHER CIRCUMSTANCES
17 WHERE WE WOULD HAVE TO HAVE SOME FLEXIBILITY OF
18 PRICING IN ORDER TO ADEQUATELY SERVE THE NEEDS OF
19 THOSE MARKETS.

20 AND THEN WITH RESPECT TO ACCESS FOR PEOPLE
21 WHO HAVE NO OTHER FORM OF ACCESS, THEY DON'T QUALIFY
22 FOR GOVERNMENT PROGRAMS AND THEY DON'T HAVE
23 INSURANCE, WE HAVE SPECIFIED THAT ANY COMPANY THAT
24 DEVELOPS A PRODUCT BASED ON CIRM FUNDING AT THE TIME
25 OF COMMERCIALIZATION IN CALIFORNIA WOULD HAVE TO

BARRISTERS' REPORTING SERVICE

1 COME UP WITH AN ACCESS PLAN THAT MET THE STANDARDS
2 THEN EXISTENT IN THE INDUSTRY FOR PROVIDING VERY LOW
3 PRICE OR FREE GOODS TO INDIVIDUALS WHO HAVE NO
4 WHEREWITHAL TO PAY FOR IT.

5 MANY COMPANIES, MYRTLE POTTER'S FORMER
6 EMPLOYER, GENENTECH, FOR EXAMPLE, HAVE THESE
7 PROGRAMS IN PLACE. ALMOST ALL SIGNIFICANT BIO-PHRMA
8 COMPANIES AND PHRMA COMPANIES HAVE SUCH PROGRAMS IN
9 PLACE TO PROVIDE MATERIALS AT EITHER NO COST OR VERY
10 LOW COST TO PEOPLE WHO HAVE NO OTHER MEANS OF
11 ACCESSING THESE THINGS.

12 SO WE HAVE DEALT WITH THE WHOLE PANOPLY OF
13 DIFFERENT ISSUES AROUND IP. I THINK OUR PROCESS IS
14 GENERALLY HAILED AS A VERY PROGRESSIVE PROGRAM THAT
15 WE PUT IN PLACE IN THE STATE. WE HAVE DEALT
16 DECISIVELY, WE BELIEVE, WITH THESE TWO IMPORTANT
17 ASPECTS OF ACCESS, PRICES FOR THINGS PAID FOR WITH
18 GOVERNMENT FUNDING OR FOR PEOPLE WHO HAVE NO OTHER
19 MEANS TO PAY IN OUR PROCESS.

20 I BELIEVE WE HAVE DRIVEN THE INDUSTRY TO
21 THE POINT OF -- WHAT SHALL I SAY? NO RETURN IS NOT
22 THE RIGHT TERM I'M LOOKING FOR -- TO THE POINT OF
23 INDIFFERENCE IN MANY CASES ABOUT WHETHER THEY WILL
24 OR WILL NOT ACCEPT CIRM FUNDING. AND WE HAVE
25 SEVERAL COMPANIES WHO HAVE DECIDED TO OPT OUT OF

BARRISTERS' REPORTING SERVICE

1 CIRM FUNDING BECAUSE THEY FIND OUR IP POLICIES
2 ONEROUS, AND THEY DON'T BELIEVE THAT THEY SHOULD
3 BE -- THAT THE FUNDING FROM CIRM REALLY REPRESENTS
4 ENOUGH OF A HELP TO THEM TO ESSENTIALLY FURTHER
5 THEIR GOALS AS COMPANIES.

6 YOU KNOW, WE BELIEVE WE'RE ON SOLID GROUND
7 WITH THE PROGRAM. IT'S UNFORTUNATE THERE ARE SOME
8 COMPANIES WHO APPARENTLY HAVE DECIDED NOT TO
9 PARTICIPATE BECAUSE OF THIS. I BRING THIS UP TO YOU
10 BECAUSE I THINK IT DOES SHOW THAT, I BELIEVE, WE'VE
11 PUSHED OUR IP POLICIES AND OUR PRICING POLICIES
12 ESSENTIALLY TO THE LIMIT OF WHAT'S ACCEPTABLE TO OUR
13 COLLEAGUES IN THE INDUSTRY AS A WHOLE.

14 THIS IS IMPORTANT BECAUSE THE THINGS I
15 MENTIONED TO YOU FIRST, THE PRICING, ETC. FOR THINGS
16 VERSUS STATE FUNDS AND THE RETURNS TO THE STATE ARE
17 DIRECT RETURNS TO THE STATE. IN THE LONG RUN,
18 LIKELY THE BIGGEST RETURN TO THE STATE WILL BE
19 BUILDING A MORE ROBUST BIOTECHNOLOGY INDUSTRY THAN
20 WE HAVE TODAY BASED ON STEM CELL TECHNOLOGY, WHICH
21 WILL CREATE JOBS IN CALIFORNIA, WILL CREATE, YOU
22 KNOW, A ROBUST GROUP OF EVENTUAL TAXPAYERS IN THE
23 STATE OF CALIFORNIA.

24 SO WE THINK THE FACT THAT NO ONE IS
25 TOTALLY HAPPY WITH THIS POLICY TODAY SAYS WE

BARRISTERS' REPORTING SERVICE

1 PROBABLY REACHED SOME KIND OF HAPPY MEDIUM HERE OR
2 UNHAPPY MEDIUM DEPENDING ON YOUR PERSPECTIVE, BUT
3 WE'VE HAD AN EXTREMELY THOROUGH PROCESS. WE'VE
4 GOTTEN INPUT FROM ALL SEGMENTS. WE HAVE A PROGRAM
5 WHICH IS WORKABLE AND WE THINK IS A PROGRAM THAT WE
6 CAN LIVE WITH GOING FORWARD. AND WE'RE SORRY THERE
7 WILL BE SOME PEOPLE WHO DECIDE TO OPT OUT, BUT
8 THAT'S THE CHOICE THAT THEY HAVE TO MAKE. I'D BE
9 HAPPY TO ANSWER ANY QUESTIONS YOU HAVE ABOUT THE
10 PROCESS.

11 CHAIRMAN CHIANG: THANK YOU. ARE THERE
12 ANY QUESTIONS?

13 MEMBER BRUNNER: WHO DETERMINES
14 ELIGIBILITY FOR THE REDUCED PRICING? I MEAN
15 SOMEBODY IS ON MEDI-CAL, AND THEY PROBABLY ALL
16 DIFFER. A NUMBER OF PEOPLE THAT ARE UNINSURED AND
17 POOR, HOW IS THAT DETERMINED?

18 DR. PENHOET: YES. THERE ARE TWO
19 COMPONENTS. ONE IS ANY GOVERNMENT FUNDS, WHETHER
20 THEY'RE STATE FUNDS, COUNTY FUNDS, CITY FUNDS, ETC.,
21 OUR PROCESS FOR PRICING WOULD REFER TO ANY THERAPY
22 PAID FOR WITH PUBLIC FUNDS. HOWEVER, IF THERE ARE
23 INDIVIDUALS WHO DON'T QUALIFY FOR ANY PUBLIC
24 ASSISTANCE WHATSOEVER AND THEY'RE TOTALLY ON THEIR
25 OWN WITH RESPECT TO HAVING TO PAY, WHAT WE'RE ASKING

BARRISTERS' REPORTING SERVICE

1 IS THAT THE COMPANY PROVIDE FOR US AND WE WILL
2 REVIEW IN PUBLIC HEARINGS AN ACCESS PLAN WHICH
3 ESSENTIALLY DEALS WITH THIS ISSUE AT THE TIME.

4 IT'S A LITTLE HARD TO PREDICT TODAY
5 EXACTLY WHAT THE FORM OF THESE THERAPIES WILL BE
6 THAT EMERGE FROM STEM CELL RESEARCH. BUT THERE IS A
7 STRONG SERIES OF PRECEDENTS WHICH HAVE BEEN SET BY
8 THE EXISTING BIOTECH AND PHARMA INDUSTRIES, AND SO
9 WHAT OUR GUIDELINES SAY IS THAT COMPANIES WILL HAVE
10 TO PROVIDE A PROGRAM BEFORE THEY COMMERCIALIZE THE
11 PRODUCT WHICH IS COMPETITIVE WITH INDUSTRY STANDARDS
12 AT THE TIME AND WHICH MEANINGFULLY ADDRESSES THE
13 NEED THAT THESE PEOPLE MIGHT HAVE.

14 BUT THE DEFINITION IN EACH CASE WOULD BE
15 TO SOME DEGREE EMBODIED IN THAT PROPOSAL THEY BRING
16 TO US, WHICH WE WILL DISCUSS IN PUBLIC HEARINGS, AND
17 THEN MAKE SOME SORT OF DETERMINATION OF WHETHER
18 THEY'VE ADEQUATELY MET IT OR NOT.

19 MEMBER BRUNNER: OKAY. AND I ASSUME THAT
20 POLICY ENDS AT THE CALIFORNIA BORDER WITH THAT?

21 DR. PENHOET: YES. I WANT TO BE CLEAR
22 ABOUT THAT. WE HAVE STUDIOUSLY TRIED TO NOT SET
23 POLICY FOR THE ENTIRE COUNTRY. WE'RE TRYING TO SET
24 POLICY FOR CALIFORNIA. INEVITABLY, THOUGH, WHAT
25 WE'RE DOING HERE DOES SET POLICY FOR THE REST OF THE

BARRISTERS' REPORTING SERVICE

1 COUNTRY. WE ARE FAR AHEAD OF ANY OTHER STATE, SO
2 MANY OTHER STATE AGENCIES, AS YOU KNOW, NOW HAVE
3 STEM CELL PROGRAMS. MOST OF THEM ARE LOOKING TO US
4 FOR LEADERSHIP IN THIS AREA BECAUSE, FRANKLY, WE
5 STARTED FIRST, AND I THINK WE PROBABLY HAD A MORE
6 ROBUST PROCESS THAN MOST OF THOSE STATES.

7 MEMBER POTTER: I JUST WANT TO TOUCH ON
8 THIS QUESTION OF PRICING AND USING CALRX AS A
9 BENCHMARK. I LOVE THE IDEA AND I LOVE THE IDEA OF
10 WHAT THIS SENATE BILL, I GUESS IT'S LISTED, 1565 IS
11 ATTEMPTING TO DO. HOWEVER, IT DOES RUN THE RISK OF
12 DISENFRANCHISING A FAIRLY LARGE GROUP OF PATIENTS,
13 AND I DON'T BELIEVE IT'S INTENDED. BUT I WOULD JUST
14 ENCOURAGE YOU TO CONTINUE TO WORK WITH THOSE WHO ARE
15 PUTTING THIS BILL TOGETHER BECAUSE IT HAS ITS FLAWS.

16 AGAIN, IT'S UNINTENDED, BUT YOU WILL HAVE,
17 WE WILL HAVE DISEASE GROUPS OF EVERY SORT IN A
18 FIRESTORM ALL CHASING US OVER THIS BILL IF WE DON'T
19 FIX THESE GAPS IN IT. AND AS YOU HAVE ATTEMPTED TO
20 DO, TRY TO DEAL WITH SOME OF THESE THINGS WITHIN
21 YOUR REGS BECAUSE THE WHOLE POINT OF THIS IS NOT TO
22 LEAVE ANYBODY OUT. YOU'VE GOT A THERAPY; STATE
23 FUNDS HAVE GONE TOWARD MAKING IT AVAILABLE. WE
24 CAN'T HAVE LEGISLATION THAT FLIES IN THE FACE OF
25 THAT AND EXCLUDES CERTAIN CLASSES OF PEOPLE.

BARRISTERS' REPORTING SERVICE

1 DR. PENHOET: THANK YOU. WHAT WE'RE
2 BEGGING FOR IS FLEXIBILITY IN THIS REGARD BECAUSE WE
3 CAN'T PREDICT THE FUTURE WITH RESPECT TO THIS. SO
4 FOR THE REASONS BOB ARTICULATED EARLIER WITH RESPECT
5 TO ORPHAN DISEASES, FOR EXAMPLE, WE WILL NEED SOME
6 FLEXIBILITY TO DO THAT. AND OUR CONCERN ABOUT 1565
7 IS THAT FOR IT TO BE CHANGED, YOU NEED ANOTHER VOTE
8 OF TWO-THIRDS OF THE LEGISLATURE, 70 PERCENT OF THE
9 LEGISLATURE, AND APPROVAL OF THE THEN GOVERNOR,
10 WHOEVER THAT HAPPENS TO BE. SO IT MINIMIZES THE
11 FLEXIBILITY. I THINK THAT'S THE CRITICAL ISSUE FOR
12 US GOING FORWARD.

13 OUR OWN POLICY ADDRESSES IN ALMOST EXACTLY
14 THE SAME LANGUAGE THE VERY FEATURES OF ACCESS,
15 EITHER FREE GOODS OR VERY LOW PRICED GOODS OR LOW
16 COST TO PUBLIC AGENCIES, THAT ARE EMBODIED IN THAT
17 BILL. SO THAT'S ONE OF OUR BIGGEST CONCERNS ABOUT
18 THE BILL. THANK YOU FOR MENTIONING THAT HERE.

19 MEMBER POTTER: IT'S NOT THAT I DON'T
20 AGREE WITH TRYING TO DEAL WITH LEGISLATION, BUT SOME
21 OF PEOPLE WHO NEEDS DRUGS, THEY'LL BE DEAD, QUITE
22 FRANKLY, BY THE TIME A LEGISLATIVE MOVE WOULD BE
23 ABLE TO COME INTO EFFECT. WE'RE IN A POSITION NOW
24 WE CAN DO SOMETHING ABOUT THAT, SO WE SHOULD FIX
25 THAT.

BARRISTERS' REPORTING SERVICE

1 DR. PENHOET: THANK YOU.

2 MR. KLEIN: IF I CAN FOLLOW UP ON THAT
3 COMMENT. IN WORKING WITH SENATOR KUEHL'S STAFF, WE
4 HAVE POINTED OUT TO THEM THAT, AS DR. PENHOET HAS
5 JUST INDICATED, IF WE'RE IN A POSITION WHERE WE HAVE
6 RIGID PRICING RULES AND WE CAN'T ADDRESS IT WITH OUR
7 REGULATIONS TO ADDRESS WHETHER IT'S ALZHEIMER'S OR
8 ORPHAN DISEASES OR OTHER SITUATIONS LIKE THAT, MANY
9 OF THESE ORPHAN DISEASES WITH CRITICALLY SHORT LIFE
10 SPANS BEFORE YOU HAVE IRREVERSIBLE DAMAGE, WE'RE IN
11 A POSITION WHERE TO GO BACK TO THE LEGISLATURE IF
12 IT'S EMBRYONIC THERAPY, WE PREDICTABLY WOULD FIND IT
13 IMPOSSIBLE TO GET A 70-PERCENT VOTE.

14 I MEAN THE CO-AUTHOR ON THIS BILL WE KNOW
15 HAS CAMPAIGNED AGAINST PROPOSITION 71 AND HAS A
16 STATED POSITION AGAINST EMBRYONIC STEM CELL
17 RESEARCH. AND ALL OF THE MEMBERS OF THAT CAUCUS ARE
18 VOTING EN BLOC FOR THIS BILL, WHICH TELLS YOU
19 SOMETHING ABOUT THEIR VIEW OF WHETHER OR NOT
20 EMBRYONIC STEM CELLS WILL BE ALLOWED TO ADVANCE.

21 THE CO-AUTHOR ALSO HAS A PROVISION IN THIS
22 BILL TO REDUCE THE VOTING PERCENTAGE REQUIRED TO
23 MOVE SOMETHING OTHER THAN STEM CELL RESEARCH TO THE
24 BOARD FOR APPROVAL. THE CO-AUTHOR'S POSITION IS TO
25 ELIMINATE THE INITIATIVE'S REQUIREMENT, THAT IF IT'S

BARRISTERS' REPORTING SERVICE

1 NOT PLURIPOTENT AND PROGENITOR STEM CELL RESEARCH,
2 YOU NEED A TWO-THIRDS VOTE FOR OTHER VITAL RESEARCH
3 OPPORTUNITIES FOR THE VERY REASON MR. LIPSON TALKED
4 ABOUT. THE VOTERS APPROVED STEM CELL RESEARCH, NOT
5 OTHER RESEARCH. AND THE CO-AUTHOR ON THE BILL,
6 SENATOR RUNNER, DOESN'T WANT EMBRYONIC STEM CELL
7 RESEARCH OR RELATED RESEARCH TO HAVE A PRIORITY
8 UNDER THE INITIATIVE, WHICH, OF COURSE, WAS THE
9 PURPOSE OF THE INITIATIVE.

10 AND SO WE FIND IT A VERY SERIOUS PROBLEM
11 WHEN FACED WITH THE SUGGESTION THAT IF THERE'S A
12 PROBLEM, WE CAN GO BACK TO THE LEGISLATURE BECAUSE
13 IF IT'S AN EMBRYONIC STEM CELL RESEARCH THERAPY,
14 WE'LL NEVER GET THOSE VOTES TO GET TO 70 PERCENT FOR
15 AMENDMENT OF THIS BILL. SO I HAVE GREAT RESPECT FOR
16 SENATOR KUEHL. SHE'S GOT TREMENDOUS OBLIGATIONS IN
17 TRYING TO DEAL WITH THE BUDGET, AND I'M HOPEFUL THAT
18 SHE CAN REDIRECT ENOUGH TIME BECAUSE, AS IT SITS
19 RIGHT NOW, THE BOARD HAS UNANIMOUSLY OPPOSED IT.

20 FINALLY, AS AN ENDING NOTE, I WOULD SAY
21 THAT CERTAINLY MYRTLE POTTER WOULD KNOW, HAVING BEEN
22 IN GENENTECH FOR MANY YEARS BEFORE A MEDICAL CRISIS
23 THAT CAUSED HER TO GO AFFORDABLE HOUSING TO
24 CONTRIBUTE TO THE SOCIETY IN ANOTHER WAY, BUT IT IS
25 VERY DIFFICULT TO MOVE FROM RESEARCH TO HUMAN

BARRISTERS' REPORTING SERVICE

1 CLINICAL TRIALS.

2 AND ONE OF THE PIECES OF LITERATURE YOU
3 HAVE BEFORE YOU IS ONE OF CATRIONA JAMIESON, WHO IS
4 A YOUNG WOMAN IN HER EARLY 30S. WE FUNDED FIRST A
5 FIRM SCHOLAR IN HER LABS UNDER OUR TRAINING
6 PROGRAMS BACK IN THE END OF 2006, AND THIS PERSON
7 WORKED UNDER CATRIONA JAMIESON ON A MYELOPROLIFIC
8 BLOOD DISEASE WHERE THE RED BLOOD CELLS DUPLICATE
9 OUT OF CONTROL AND IN A SIGNIFICANT NUMBER OF CASES
10 LEAD TO LEUKEMIA.

11 WE THEN FUNDED HER SEED MONEY GRANT TO
12 FURTHER FOCUS ON HER RESEARCH IN THIS AREA. SO 18
13 MONTHS AFTER THIS FUNDING, SHE IS NOW IN HUMAN
14 CLINICAL TRIALS. HUMAN CLINICAL TRIALS 18 MONTHS
15 LATER. NOW, SHE USED THE STEM CELL RESEARCH TO
16 UNDERSTAND THE NATURE OF THE DISORDER AND THE
17 BIOLOGICAL DEFECTS IN THE HUMAN MECHANISM THAT WAS
18 CAUSING THIS UNCONTROLLED REPLICATION OF RED BLOOD
19 CELLS, AND THEN WENT TO TARGAGEN, A SAN DIEGO
20 COMPANY, WHO HAD A SMALL MOLECULE THAT THEY KNEW
21 COULD AFFECT THIS PARTICULAR GENE, THEN BROUGHT THEM
22 TOGETHER INTO A PARTNERSHIP THAT IS NOW PROVIDING
23 HUMAN THERAPIES IN SAN DIEGO TO INDIVIDUALS WHO ARE
24 PART OF A HUNDRED THOUSAND PERSON GROUP IN THIS
25 COUNTRY THAT SUFFERS FROM THIS DISEASE.

BARRISTERS' REPORTING SERVICE

1 IT IS NOT GOING TO CHANGE THE WORLD
2 BECAUSE IT'S NOT A BLOCKBUSTER THERAPY APPLICATION,
3 BUT IT IS REMARKABLE TO THE DEDICATION OF THE
4 SCIENTISTS IN THIS AREA THAT WE HAVE A THERAPY
5 THAT'S HELPING PATIENTS, AND EVERY PATIENT LIFE WE
6 HELP SAVE IS A VERY VITAL, SACRED RESOURCE OF THIS
7 STATE AND THIS NATION.

8 SO I WOULD SAY THAT WE ARE VERY PROUD OF
9 WHAT WE HAVE DONE. WE'RE OPEN TO ANY FURTHER
10 QUESTIONS, BUT WE BELIEVE VERY MUCH IN THE AGENCY
11 AND WE BELIEVE THAT, HAVING GONE THROUGH THE
12 SCRUTINY OF ALL THREE COMPONENTS OF STATE
13 GOVERNMENT, THE COURTS, THE LEGISLATURE, AND THE
14 CONTROLLER'S OFFICE REPRESENTING THE EXECUTIVE
15 BRANCH, THAT WE HAVE SHOWN THAT YOU CAN HAVE AN
16 EXPERT PANEL THAT CONTRIBUTES GREAT KNOWLEDGE, BUT
17 HAS STRICT CONTROLS ON CONFLICTS, AS THE COURT SAYS,
18 BALANCING THE NECESSITY OF KNOWLEDGE AND CONTROLLING
19 AND AVOIDING ABUSE. THANK YOU VERY MUCH. IT'S A
20 PRIVILEGE TO ADDRESS YOU.

21 CHAIRMAN CHIANG: BOB, QUICKLY CAN YOU
22 EXPLAIN THE LOAN PROGRAM AND IF IT'S GOING TO BE
23 GOVERNED IN REGARDS TO CONFLICTS OF INTEREST AS THE
24 GRANTS?

25 MR. KLEIN: THE LOAN PROGRAM WILL BE

BARRISTERS' REPORTING SERVICE

1 COVERED BY EVERY PROVISION OF CONFLICTS OF INTEREST
2 AS THE GRANTS PROGRAM. THE LOAN PROGRAM, AS
3 CONCEIVED, IS SUBJECT TO REPORT TO BOARD AND BOARD
4 ACTION IN AUGUST, IN THE AUGUST MEETING OF THIS
5 YEAR. IT IS AN ATTEMPT, WHEN WORKING WITH NEW
6 THERAPIES, TO STRETCH OUR STATE DOLLARS SO THAT
7 WE'RE MAKING LOANS WHERE WE CAN, NOT JUST GRANTS.
8 AND EVEN WITH A VERY HIGH RATE OF NONPERFORMANCE
9 BECAUSE, IN FACT, IF WE CAN GET TO PRIVATE SECTOR AT
10 THIS POINT IN THE EARLY DEVELOPMENT OF STEM CELL
11 RESEARCH, WE WOULDN'T NEED ALL OF OUR MONEY, BUT WE
12 CAN'T BECAUSE IT IS A HIGH RISK PERIOD.

13 BUT WHAT WE'VE DONE TO OFFSET THE HIGH
14 RISK, WE'VE RECOMMENDED A PROGRAM OUT OF THE TASK
15 FORCE THAT WILL HAVE WARRANT COVERAGE; THAT IS, IT
16 WILL HAVE STOCK WARRANT COVERAGE. AND THOSE
17 WARRANTS CAN BE SOLD IN ORDER TO GET A FURTHER
18 RETURN BACK TO THE PROGRAM TO RECYCLE FUNDS AND
19 OFFSET LOSSES.

20 SO FROM LOAN PROCEEDS AND WARRANT
21 PROCEEDS, WE HOPE TO HAVE A LOAN PROGRAM WHERE WE
22 CAN HAVE A VERY HIGH DEGREE OF MATCHING FUNDS FROM
23 THE PRIVATE SECTOR WHEN SOMETHING GOES INTO HUMAN
24 TRIALS WHERE IT'S NOT AN ORPHAN DISEASE. AND WE
25 HOPE THAT WE CAN WITH MATCHING FUNDS STRETCH SEVERAL

BARRISTERS' REPORTING SERVICE

1 HUNDRED MILLION DOLLARS INTO DOUBLE THAT AMOUNT AND
2 FURTHER THE AIMS OF THE RESEARCH IN THE STATE WITH
3 ALL THE CONFLICT PROVISIONS APPLYING AS HAS BEEN
4 DISCUSSED TODAY.

5 CHAIRMAN CHIANG: OKAY. THANK YOU. DOES
6 THE REPORTER OR THE MEMBERS NEED A BREAK, OR YOU
7 WANT TO CONTINUE?

8 THE REPORTER: THE REPORTER IS FINE.

9 CHAIRMAN CHIANG: OKAY. NEXT ITEM IS ITEM
10 NO. 10 REGARDING SB 1565. IF WE COULD HAVE LARK
11 PARK FROM SENATOR KUEHL'S OFFICE.

12 MS. PARK: GOOD AFTERNOON. MY NAME IS
13 LARK PARK. I'M A STAFF CONSULTANT OF THE SENATE
14 HEALTH COMMITTEE AND THE STAFF CONTACT FOR SB 1565
15 AUTHORED BY SENATORS KUEHL AND RUNNER.

16 I WANT TO EXPRESS THANKS TO THE COMMITTEE
17 ON BEHALF OF THE TWO SENATORS WHO COULD NOT MAKE IT
18 TODAY TO PRESENT THE BILL FOR THE COMMITTEE
19 THEMSELVES. THEY HAVE FISCAL COMMITTEES MEETING IN
20 THE SENATE, AND THE SENATE IS IN SESSION TODAY. AND
21 I WANT TO THANK THE COMMITTEE FOR ALLOWING ME TO
22 APPEAR ON THEIR BEHALF.

23 I ALSO WANT TO THANK CHAIRMAN KLEIN AND
24 VICE CHAIR PENHOET AND BOARD MEMBER POTTER FOR THEIR
25 REMARKS ON THE PRICING PROVISIONS OF CALRX CONTAINED

BARRISTERS' REPORTING SERVICE

1 IN BOTH THE MEASURE AND IN THE PROPOSED REGULATIONS
2 THAT CIRM IS CURRENTLY CIRCULATING. I'D LIKE TO
3 ADDRESS THEIR COMMENTS IN A LITTLE BIT LATER PART OF
4 MY PRESENTATION OF THE BILL WHERE APPROPRIATE.

5 THE BILL MAKES A FEW IMPORTANT CHANGES
6 REGARDING HOW CIRM CARRIES OUT THE MISSION VOTERS
7 HAVE ENTRUSTED TO IT IN THE AREA OF STEM CELL
8 RESEARCH. FIRST, THE BILL CODIFIES CERTAIN
9 REQUIREMENTS REGARDING ACCESS TO NEW THERAPIES BY
10 THE UNINSURED AND THE PRICE THAT WE PAY FOR THEM
11 THROUGH PUBLIC PROGRAMS ONLY.

12 SECOND, THE BILL ASKS THE LITTLE HOOVER
13 COMMISSION TO LOOK AT THE GOVERNANCE STRUCTURE OF
14 CIRM AND THE ICOC.

15 AND THEN, THIRDLY, THE BILL MAKES A CHANGE
16 REGARDING THE VOTE THRESHOLD NECESSARY TO FUND, FOR
17 ALL INTENTS AND PURPOSES, NONEMBRYONIC STEM CELL
18 RESEARCH, WHICH I BELIEVE THAT THE INSTITUTE ALREADY
19 CAN FUND AND DOES FUND. AND I'LL MAKE BRIEF POINTS
20 ON EACH OF THE PROVISIONS OF THE BILL.

21 WITH REGARD TO CODIFYING THE ACCESS
22 REQUIREMENTS TO NEW THERAPIES, CURRENTLY THERE ARE
23 MINOR DIFFERENCES BETWEEN WHAT THE BILL PROPOSES AND
24 WHAT THE DRAFT REGULATIONS PROPOSE. WITH REGARD TO
25 THE REQUIREMENT TO SUBMIT AN ACCESS PLAN FOR THE

BARRISTERS' REPORTING SERVICE

1 UNINSURED TO CIRM PRIOR TO COMMERCIALIZATION, CIRM'S
2 REGS CURRENTLY SPECIFY 90 DAYS PRIOR TO
3 COMMERCIALIZATION UNLESS THE AGENCY AGREES TO A
4 SHORTENED TIMEFRAME. THE BILL IS SILENT ON THE
5 MATTER IN TERMS OF THE NUMBER OF DAYS.

6 WITH REGARD TO THE REQUIREMENT FOR CIRM TO
7 ACTUALLY APPROVE THIS PLAN AFTER A PUBLIC HEARING,
8 BOTH ARE RATHER SILENT ON WHAT THE PLAN SHALL
9 CONTAIN OR AT WHAT PRICE THE UNINSURED MAY PURCHASE
10 THESE THERAPIES. THE CIRM REGULATIONS DO SPECIFY
11 THAT THE PLANS HAVE TO BE CONSISTENT WITH INDUSTRY
12 STANDARDS, AND THE BILL MAKES NO REFERENCE TO
13 LANGUAGE REGARDING INDUSTRY STANDARDS.

14 WITH REGARD TO PRICING, BOTH THE BILL AND
15 THE REGULATIONS DO REFERENCE CALRX AND ITS BENCHMARK
16 PRICES. AND JUST TO GIVE A BRIEF OVERVIEW ON CALRX,
17 CALRX WAS PUT INTO LAW BY AB 2911 IN 2006, AUTHORED
18 BY SPEAKER NUNEZ OR THEN SPEAKER NUNEZ, AND IT IS
19 THE STATE'S PRESCRIPTION DRUG PROGRAM FOR
20 CALIFORNIANS UP TO 300 PERCENT OF THE FEDERAL
21 POVERTY LEVEL AND CERTAIN OTHER INDIVIDUALS, AND IT
22 HAS YET TO BE IMPLEMENTED DUE TO THE STATE'S FISCAL
23 SITUATION.

24 I BELIEVE CURRENTLY THE ITEM IS IN
25 CONFERENCE NOW IN TERMS OF WHETHER IT WILL BE FUNDED

BARRISTERS' REPORTING SERVICE

1 FOR THE NEXT FISCAL YEAR. I DON'T KNOW AT PRESENT.

2 TO ADDRESS THE MINOR DIFFERENCES, SB 1565
3 REQUIRES GRANTEES AND LICENSEES TO OFFER OR TO SELL
4 THE DRUGS TO PUBLIC PROGRAMS AT ONE OF THE THREE
5 BENCHMARK PRICES IN CALRX AS THE PROGRAM EXISTS ON
6 JANUARY 1, 2008. THE REGULATIONS CURRENTLY SAY
7 CALRX OR A SUCCESSOR PROGRAM. WE BELIEVE THAT THE
8 JANUARY 1, 2008, DATE IS BETTER AS WE KNOW WHAT
9 THESE BENCHMARKS ARE AT THIS POINT IN TIME. WE
10 WOULD NOT KNOW WHAT BENCHMARKS MAY BE USED IN A
11 SUCCESSOR PROGRAM, WHICH COULD BE BETTER OR WHICH
12 COULD BE WORSE, SO WE THINK IT'S APPROPRIATE TO DO
13 WHAT WE CURRENTLY KNOW IS THE CASE IN CALRX.

14 THE BILL HAS WORDING CURRENTLY THAT DOES
15 SAY DOES NOT EXCEED ANY BENCHMARK PRICE IN CALRX.
16 AND BASED ON RECENT INPUT FROM CIRM, WE ARE AMENDING
17 THE LANGUAGE TO BE MORE CLEAR, THAT THE REQUIREMENT
18 ONLY APPLIES TO, FIRST, PUBLIC PROGRAMS, WHICH I
19 THINK IT IS AMPLY CLEAR, BUT TO MAKE EVEN MORE
20 CLEAR, AND THAT THE REQUIREMENT IS TO SELL IT -- THE
21 DRUG THAT IS IN PART OR WHOLE FUNDED BY CIRM
22 DOLLARS, NOT AT THE LOWEST BENCHMARK PRICE IN CALRX,
23 BUT AT ANY ONE OF THE BENCHMARK PRICES IN CALRX.

24 I DO WANT TO NOTE FOR THE COMMITTEE THAT
25 SENATORS KUEHL AND RUNNER RECENTLY SENT A LETTER TO

BARRISTERS' REPORTING SERVICE

1 THE MEMBERS OF THE ICOC MAKING THIS ABSOLUTELY CLEAR
2 AND COMMITTING IN WRITING TO MAKE THIS AMENDMENT TO
3 REMOVE ANY CONFUSION.

4 A BILL LAST YEAR DID USE MEDICAID BEST
5 PRICE LANGUAGE, AND THE BILL THAT IS CURRENTLY IN
6 THE LEGISLATURE CLEARLY MOVES AWAY FROM THAT.

7 SO TO TALK ABOUT THE COMMENTS ABOUT THE
8 CALRX BENCHMARKS, WHICH I THINK VICE CHAIR PENHOET
9 DID GO OVER, THAT IT INVOLVES MEDICAID BEST PRICE,
10 85 PERCENT OF AVERAGE MANUFACTURER PRICE, AND LOWEST
11 COMMERCIAL PRICE. AND I REALLY DO WANT TO STRESS
12 THAT LOWEST COMMERCIAL PRICE MEANS A PRICE THAT IS
13 SOLD TO A NONPUBLIC ENTITY, SUCH AS KAISER. SO WHAT
14 THE BILL WOULD REQUIRE IS YOU HAVE TO GIVE US A
15 PRICE AT LEAST AS GOOD AS KAISER.

16 WE BELIEVE THAT THE STATE, AS IT HAS
17 PLAYED A ROLE IN FUNDING AND UNDERWRITING THESE
18 THERAPIES, SHOULD GET A PRICE AT LEAST AS GOOD AS A
19 KAISER. I WANT TO UNDERSCORE THAT EACH OF THESE
20 BENCHMARKS ARE A FLUID AND MARKET-BASED PRICE. DRUG
21 MANUFACTURERS SET THE PRICE. A KAISER WILL
22 NEGOTIATE DOWNWARDS AS MUCH AS THEY CAN, BUT BY NO
23 MEANS IS THIS A PRICE CAP. IT IS BASED ON WHAT THE
24 MARKET IS AT FOR EACH INDIVIDUAL THERAPY. SO WE
25 BELIEVE WE ARE IN SYNC WITH CIRM ON THE CALRX

BARRISTERS' REPORTING SERVICE

1 BENCHMARKS.

2 TO ADDRESS THE ORPHAN DRUG ISSUE, WHICH IS
3 SOMETHING THAT CHAIRMAN KLEIN WAS GOOD ENOUGH TO
4 SPEAK WITH STAFF ABOUT PRIOR TO THE JULY 4TH
5 HOLIDAY, THE ORPHAN DRUG ISSUE IS ONE THAT WE HAVE
6 NOT DISCUSSED YET WITH SENATORS KUEHL AND RUNNER,
7 BUT WILL BE DOING. AND SO I CAN'T TELL YOU WHERE
8 THE AUTHORS ARE WITH REGARD TO ANY COMMITMENT
9 REGARDING THAT LANGUAGE. AND CERTAINLY WE DON'T
10 WANT TO SEE PEOPLE BEING DENIED THERAPIES BASED ON
11 THE FACT THAT IT SERVES AN ORPHAN DISEASE OR RARE
12 DISEASE OR RARE CONDITION.

13 THAT BEING SAID, THE BENCHMARK IN CALRX IS
14 STILL LOWEST COMMERCIAL PRICE FOR AN ORPHAN DISEASE.
15 SO TO THE EXTENT THAT KAISER PAYS A CERTAIN PRICE,
16 THAT IS ALL THAT A GRANTEE OR LICENSEE HAS TO DO IS
17 TO SELL IT AT THAT SAME LOW COMMERCIAL PRICE TO A
18 KAISER. THAT'S THE EXAMPLE.

19 CURRENTLY MY UNDERSTANDING IS THAT WITH
20 REGARD TO THE ORPHAN DRUG ACT OF 1983, THAT THERE
21 ARE SEVERAL INCENTIVES TO ACTUALLY BRING THESE
22 THERAPIES FOR RARE DISEASES AND CONDITIONS TO
23 MARKET, SUCH AS SEVEN-YEAR PATENT PROTECTION WITHOUT
24 HAVING TO ACTUALLY GO THROUGH THE PATENT APPLICATION
25 PROCESS, A CERTAIN NUMBER OF RESEARCH -- OF TAX

BARRISTERS' REPORTING SERVICE

1 BREAKS WITH REGARD TO RESEARCH AND CLINICAL TRIALS
2 AND THE COST OF GETTING THESE DRUGS TO MARKET, AS
3 WELL AS IT IS MORE DIFFICULT, I BELIEVE, TO ACTUALLY
4 GET GENERICS ON THESE ORPHAN DRUGS, EVEN AFTER A
5 PATENT EXPIRES.

6 BUT WE STILL ARE TRYING TO UNDERSTAND WHY
7 LOWEST COMMERCIAL PRICE IS A DIFFICULTY. AND WITH
8 REGARD TO THE EXAMPLE THAT CHAIRMAN KLEIN MENTIONED
9 ABOUT A GROUP THAT WILL NOT TAKE CIRM MONEY TO
10 FURTHER THE CLINICAL TRIALS, I GUESS HE DID BRING
11 THIS UP IN OUR MOST RECENT DISCUSSION, BUT IT WAS
12 UNCLEAR WHY, AGAIN, LOWEST COMMERCIAL PRICE WAS A
13 BARRIER IN THAT REGARD. BUT WE WILL HAVE -- AS THE
14 BILL MOVES FORWARD, WE DO INTEND TO HAVE FURTHER
15 DISCUSSIONS WITH CIRM TO SEE HOW FLEXIBILITY MAY BE
16 PUT INTO THE MEASURE TO ADDRESS THESE PARTICULAR
17 CONCERNS.

18 WITH REGARD TO THE TIMEFRAME UNDER WHICH
19 THE LEGISLATURE MAY MOVE, BECAUSE THIS BILL -- I'M
20 SORRY -- BECAUSE ANY MEASURE THAT AMENDS PROP 71
21 REQUIRES A 70-PERCENT VOTE OF THE LEGISLATURE, ANY
22 MEASURE ACTUALLY CAN MOVE ON AN URGENCY BASIS, WHICH
23 MEANS THAT THERE IS NO YEARLONG WAIT TIME. YOU CAN
24 ACTUALLY HAVE SOMETHING GO THROUGH ALL THE POLICY
25 AND FISCAL COMMITTEES OF THE LEGISLATURE AND GET

BARRISTERS' REPORTING SERVICE

1 SIGNED BY THE GOVERNOR ON A VERY EXPEDITED BASIS.
2 ANYTHING THAT HAS A TWO-THIRDS VOTE AND HAS AN
3 URGENCY CLAUSE IN THE MEASURE CAN BE DONE IN THAT
4 FASHI ON.

5 AND IN THAT REGARD, I DON'T KNOW WHETHER
6 THAT MIGHT BE EVEN FASTER THAN HOW CIRM CAN MOVE
7 FORWARD IN ITS REGULATORY PROCESS, WHICH REQUIRES A
8 CERTAIN NUMBER OF DAYS FOR PUBLIC COMMENT AND THE
9 LIKES. SO THAT CERTAINLY IS NO IMPEDIMENT, I
10 BELIEVE. AND I WILL ADDRESS CHAIRMAN KLEIN'S
11 COMMENTS ON THE TWO-THIRDS VOTE IN JUST A MINUTE.

12 SO THERE ARE TWO ADDITIONAL THINGS THAT
13 THE BILL ADDRESSES THAT ARE OUTSIDE SORT OF THE
14 REGULATIONS AND THE COMPARISON THAT I'VE DONE. ONE
15 IS A REQUEST TO THE LITTLE HOOVER COMMISSION TO
16 STUDY THE GOVERNANCE STRUCTURE OF CIRM AND THE ICOC.
17 AND THIS WAS BASED MOSTLY ON SORT OF THE MANY PRESS
18 REPORTS OF BREACHES OF CONFLICT OF INTEREST
19 STANDARDS LAST FALL. I BELIEVE THE CONTROLLER'S
20 OFFICE HAS BEEN VERY ON TOP OF THESE ISSUES.

21 AND WHILE SENATORS KUEHL AND RUNNER
22 BELIEVE THAT CIRM IS REACTING APPROPRIATELY, WE
23 BELIEVE THAT CIRM AND THE ICOC COULD BENEFIT FROM A
24 LITTLE HOOVER COMMISSION STUDY TO HELP THEM AVOID
25 SUCH CONFLICTS IN THE FUTURE. THERE'S GREAT VALUE

BARRISTERS' REPORTING SERVICE

1 IN HAVING AN OUTSIDE PARTY TO SEE THINGS THAT YOU
2 MAY NOT SEE, AND THIS CAN ONLY HELP ENSURE THAT THE
3 BEST SCIENCE IS FUNDED AND THAT GRANT MAKING IS FREE
4 FROM UNDUE INFLUENCE AND EVEN THE APPEARANCE OF
5 INAPPROPRIATE INFLUENCE.

6 AND WE HOPE THAT THIS WILL ACTUALLY BUILD
7 PUBLIC CONFIDENCE AND PUBLIC TRUST IN THE INSTITUTE.
8 AND WE DON'T BELIEVE THAT THIS IS DUPLICATIVE OF ANY
9 AUDITS THAT HAVE BEEN DONE TO DATE, AND CERTAINLY WE
10 DO NOT BELIEVE THAT SUCH A STUDY BY LITTLE HOOVER
11 WOULD INTERFERE WITH ANY OF THE GRANT MAKING
12 SCHEDULE OR ABILITY OF CIRM.

13 LASTLY, THE MEASURE CHANGES THE VOTE
14 THRESHOLD REQUIRED TO FUND RESEARCH THAT MAY ALSO
15 RECEIVE FEDERAL FUNDS PROVIDED IT IS A VITAL
16 RESEARCH OPPORTUNITY. THIS AMENDMENT WAS MOTIVATED
17 BY BREAKTHROUGHS IN NONEMBRYONIC STEM CELL RESEARCH
18 OVER THE LAST YEAR. CIRM CURRENTLY CAN AND DOES
19 FUND NONEMBRYONIC STEM CELL RESEARCH, AS WE'VE BEEN
20 TOLD. AND MY UNDERSTANDING ALSO IS THAT THESE VOTES
21 HAVE BY AND LARGE BEEN UNANIMOUS, THAT THEY HAVE NOT
22 BEEN CLOSE AT ALL.

23 THE CORE MISSION REMAINS UNCHANGED, TO
24 FUND RESEARCH THAT THE FEDERAL GOVERNMENT IS NOT
25 FUNDING, AND THAT ANY FUNDING OUTSIDE THIS ARENA

BARRISTERS' REPORTING SERVICE

1 MUST BE A VITAL RESEARCH OPPORTUNITY. THAT LANGUAGE
2 REMAINS UNCHANGED BY THIS BILL, AND IT LEAVES IT IN
3 THE HANDS OF SCIENTISTS, BASED ON THEIR SCIENTIFIC
4 JUDGMENT, WHAT THE MOST PROMISING THERAPIES WILL BE.

5 WHILE CHAIRMAN KLEIN DID REFERENCE THE
6 DIFFICULTY OF OBTAINING 70 PERCENT IN FUTURE
7 LEGISLATION AND NOTED THAT THIS MEASURE IS JOINTLY
8 AUTHORED BY SENATOR RUNNER, I DO WANT TO NOTE FOR
9 THE COMMITTEE THAT THIS PARTICULAR PROVISION IN THE
10 BILL WAS PUT INTO PLACE IN THE ASSEMBLY SIDE, AND
11 THAT PRIOR TO, WE HAD THE SUPPORT OF EVERY SINGLE
12 SENATE REPUBLICAN WITHOUT SUCH AN AMENDMENT THAT
13 THEY HAD NO KNOWLEDGE THAT THEY WERE EVEN PUTTING IN
14 THIS AMENDMENT, AND YET THEY SUPPORTED THIS MEASURE
15 BECAUSE OF WHAT IT DOES FOR PRICING.

16 AND WE HAVE HAD THE SUPPORT OF EVERY
17 DEMOCRAT IN THE LEGISLATURE THROUGH THE POLICY
18 COMMITTEES, THROUGH TWO POLICY COMMITTEES IN THE
19 ASSEMBLY EVEN AFTER PUTTING THIS PARTICULAR
20 PROVISION IN PLACE.

21 SO IN CLOSING, I JUST WANTED TO SAY THAT
22 SENATORS KUEHL AND RUNNER REALLY DO BELIEVE THAT
23 CIRM IS HEADED IN THE RIGHT DIRECTION. WE SIMPLY
24 WANT TO MAKE SURE THAT CIRM STAYS ON COURSE BY
25 PLACING THIS ASSURANCE IN STATUTE, THAT STEM CELL

BARRISTERS' REPORTING SERVICE

1 THERAPIES FUNDED BY CALIFORNIANS ARE GOING TO BE
2 AFFORDABLE TO ALL CALIFORNIAN, AND NOT JUST A GIFT
3 TO THE WEALTHY OR THOSE WITH GREAT INSURANCE. IN
4 GUARANTEEING THE STATE'S ABILITY TO BUY THESE
5 THERAPIES AT THE LOWEST COMMERCIAL PRICE, REALLY
6 NOTHING MORE, IS CONSISTENT WITH THE PROMISE OF PROP
7 71, AND IT ACTUALLY HAS THE POTENTIAL TO ALLEVIATE
8 PRESSURE ON THE GENERAL FUND IN FUTURE YEARS SHOULD
9 THESE THERAPIES PROVE TO BE SUCCESSFUL. AND WE HOPE
10 THAT BY CODIFYING THESE REGULATIONS, THAT DRUG
11 MANUFACTURERS WILL NOT BE ATTEMPTED TO USE THEIR
12 CONSIDERABLE MARKET POWER TO WITHHOLD
13 COMMERCIALIZATION OF PROMISING THERAPIES IN HOPES OF
14 UNDOING THE REGULATIONS THAT CIRM HAS THOUGHTFULLY
15 PUT INTO PLACE.

16 AND LASTLY, THIS \$6 BILLION INVESTMENT IS
17 VERY DEAR AS THE STATE FACES AN EXTREME FISCAL
18 CRISIS, AND THAT EVERY PROVISION IN THIS MEASURE
19 SERVES ONLY TO SAFEGUARD THIS INVESTMENT. AND I
20 JUST WANT TO HARKEN BACK TO WHAT THE CONTROLLER SAID
21 EARLIER ABOUT HINDSIGHT NOT BEING OVERSIGHT. AND SO
22 WE WOULD WANT TO DO THESE THINGS AND PUT THESE
23 PROVISIONS IN PLACE BEFORE WE FIND OUT THREE YEARS
24 DOWN THE LINE THAT NOT DOING ANYTHING PROVED TO BE
25 INADEQUATE. THANK YOU VERY MUCH.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN CHIANG: THANK YOU, MS. PARK. DO
2 ANY OF THE MEMBERS HAVE QUESTIONS? THANK YOU VERY
3 MUCH.

4 I WANTED TO ARTICULATE MY SUPPORT FOR
5 1565. I THINK AFTER THREE YEARS AND THE PATH WE'RE
6 TAKING, IT IS AN APPROPRIATE TIME TO REVIEW THE
7 GOVERNANCE OF CIRM. I THINK, AS BOTH SENATORS
8 INDICATED, THE REPRESENTATIVE, WE ARE ON THAT PATH,
9 BUT I THINK -- I ALWAYS BELIEVE IN STRONG
10 TRANSPARENCY, ELIMINATE POTENTIAL CONFLICTS OF
11 INTEREST, AND MAKING SURE THAT WE HAVE THE BEST
12 DECISION-MAKING. SO I WOULD ENCOURAGE THE REVIEW
13 AND SENDING IT TO LITTLE HOOVER COMMISSION. I
14 ALWAYS THINK THEY PROVIDE -- FOR THE MOST PART
15 PROVIDE GENERALLY INSTRUCTIVE ADVICE.

16 AND SO I HAVE DONE SO, AND FOR THOSE WHO
17 ARE INTERESTED ON THE OTHER MATTERS AS ARTICULATED
18 BY MYRTLE, I THINK THOSE COMMENTS ARE ALSO VERY,
19 VERY INSTRUCTIVE.

20 LET ME OPEN IT FOR PUBLIC COMMENT. IS
21 THERE ANYBODY WHO WOULD LIKE TO MAKE A PUBLIC
22 COMMENT?

23 MR. KLEIN: THANK YOU, MR. CHAIRMAN. LARK
24 PARK IS AN EXTREMELY GOOD ADVOCATE OF A POSITION.
25 AND, FRANKLY, PROBABLY THERE'S NOT A HAIR OF

BARRISTERS' REPORTING SERVICE

1 DIFFERENCE BETWEEN HER OBJECTIVES AND MY OBJECTIVES.
2 I'M A PATIENT ADVOCATE. WHILE I HAVE THE FUNDS TO
3 TAKE CARE OF MY SON WITH JUVENILE DIABETES, I WORRY
4 ABOUT THE 8 PERCENT TAX THAT THE STATE PUTS ON THE
5 BASICS THAT ARE USED TO TEST BLOOD SUGARS FOR
6 CHILDREN WITH DIABETES WHEN THAT MAY MEAN THEY DON'T
7 GET ONE OUT OF EVERY 12 MONTHS WORTH OF THE
8 SPECIALIZED, VERY EXPENSIVE STICKS USED TO TEST
9 BLOOD SUGARS. HOPEFULLY, I EMPATHIZE AS WELL WITH
10 THOSE PATIENTS WHO HAVE ALZHEIMER'S, EARLY ONSET
11 ALZHEIMER'S I'M WORRIED ABOUT FROM THE KNOWLEDGE
12 THAT MY MOTHER HAS ALZHEIMER'S THAT'S FAR, FAR TOO
13 ADVANCED TO EVER BENEFIT FROM ANYTHING WE'RE DOING.

14 BUT IT'S IMPORTANT TO REALIZE, AND I WOULD
15 LIKE TO EMPHASIZE THAT I THINK LARK PARK DOES SEE
16 THE ISSUES WE RAISED AND IS GOING TO TALK TO THE
17 SENATOR ABOUT FLEXIBILITY IN HOW THIS BILL IS
18 WRITTEN. BECAUSE IF YOU HAVE, WITH THE ALZHEIMER'S
19 EXAMPLE I GAVE YOU EARLIER, IF YOU HAVE A SUBGROUP
20 THAT NEEDS A DIFFERENT PRICE THAN THOSE PEOPLE
21 GETTING MEDICARE, THE FACT THAT YOU HAVE A
22 COMMERCIAL PRICE IS NOT THE END OF THE STORY.

23 THE PROBLEM HERE IS WE MAY WANT THESE
24 COMPANIES TO SELL TO KAISER FOR PEOPLE WITH EARLY
25 ONSET ALZHEIMER'S BELOW A CERTAIN INCOME LEVEL AT A

BARRISTERS' REPORTING SERVICE

1 LOWER PRICE THAN THE BASIC PRICE. WE CAN'T DO THAT
2 UNDER THIS REGULATION. WE CAN'T SERVE THIS GROUP OF
3 SPECIAL NEEDS.

4 IN FACT, THE ISSUE OF COMPASSIONATE CARE
5 IS IMPORTANT BECAUSE WE MAY WANT TO SELL -- HAVE
6 THIS COMPANY SELL TO KAISER FOR PEOPLE THAT ARE
7 UNINSURED OR MAYBE PEOPLE WHO ARE INSURED, BUT THEY
8 HAVE VERY LOW INSURANCE LIMITS. THE LOWEST INCOME
9 LEVEL, WE MAY WANT THEM TO SELL TO KAISER FOR A
10 GROUP BELOW A CERTAIN INCOME AT A LOWER PRICE. NOW,
11 THE PROBLEM IS UNDER THE LEGISLATION AS STRUCTURED,
12 IF YOU SELL AT THE LOWER PRICE, THAT BECOMES THE
13 BEST COMMERCIAL PRICE, AND YOU'VE GOT TO SELL EVERY
14 UNIT AT THAT BEST COMMERCIAL PRICE.

15 SO IT DOESN'T ALLOW US TO DIFFERENTIATE TO
16 GET TO SPECIAL NEEDS GROUP. AGAIN, WE'RE HOPEFUL
17 THAT LARK PARK, WHO IS A GREAT ADVOCATE, WILL BE
18 ABLE TO GET SOME MAJOR AMENDMENTS AS TO FLEXIBILITY.
19 AND I WOULD POINT OUT THAT THE SENATOR HAD
20 ORIGINALLY TOLD US SHE WASN'T SURE THE BILL WAS
21 NECESSARY BECAUSE WE HAD OUR REGULATIONS. SO WE
22 ONLY MEET EVERY TWO MONTHS AS A FULL BOARD. WE ONLY
23 JUST AS A BOARD TOOK A POSITION IN OPPOSITION
24 BECAUSE IT WAS CLEAR THAT THE BILL WAS MOVING
25 FORWARD. SO THERE HAS NOT PREVIOUSLY BEEN A

BARRISTERS' REPORTING SERVICE

1 POSITION WE COULD COMMUNICATE WITH THE MEMBERS, AND
2 IT'S MY UNDERSTANDING THERE'S A NUMBER OF PEOPLE IN
3 THE SENATE AND/OR THE ASSEMBLY WHO ARE ON COMMITTEES
4 THAT PREVIOUSLY HAVE HELD THIS POSITION. THEY'RE
5 GOING TO CHANGE THEIR POSITION NOW THAT THEY
6 UNDERSTAND THE OPPOSITION AND THEY UNDERSTAND THE
7 REASONS WHY.

8 IN ANY CASE IT IS AN IMPORTANT ISSUE. I
9 RECOGNIZE AND IDENTIFY WITH THE INTENT THAT THE
10 CONTROLLER IDENTIFIES WITH, THE SAME OBJECTIVES I
11 THINK I HOPE THAT I HAVE AS THE CONTROLLER HAS.
12 WE'D LIKE TO HONOR THE CONTROLLER'S OBJECTIVES IN
13 HONORING OUR MISSION. AND I THANK YOU VERY MUCH.

14 CHAIRMAN CHIANG: BOB, CAN I ASK YOU A
15 QUESTION? ARE YOU SAYING THE REGULATION DOES NOT
16 ALLOW YOU TO SELL THE PRODUCT AT A LOWER PRICE THAN
17 PROVIDED BY REGULATION?

18 MR. KLEIN: IT REQUIRES -- IT EFFECTIVELY
19 REQUIRES A SINGLE PRICE. SO IF I HAVE A SUBGROUP OF
20 SPECIAL NEED, I CAN'T DO A SECOND PRICE. IT DOESN'T
21 HAVE THAT FLEXIBILITY IN THE LEGISLATION. BY
22 REGULATION WE CAN SET AND RECOGNIZE A SUBGROUP FOR
23 EARLY ONSET BASED ON AGE, OR WE COULD SET -- WE
24 COULD HAVE A COMMERCIAL PRICE THAT WE SELL TO KAISER
25 FOR ONE GROUP, AND THEN WE CAN HAVE A LOWER PRICE WE

BARRISTERS' REPORTING SERVICE

1 SELL TO KAISER TO TRY AND GET THEM TO DELIVER
2 THERAPIES TO A LOWER GROUP.

3 RIGHT NOW ADULT STEM CELL THERAPIES ARE
4 BEING DENIED AT TIMES BY HMO'S BECAUSE OF THE FACT
5 THAT THEY CAN'T DEAL WITH THE PRICING. SO THE ISSUE
6 IS FOR CERTAIN ECONOMIC GROUPS THAT HAVE LOWER
7 INSURANCE OR OTHER PROBLEMS, WE NEED TO BE ABLE TO
8 DIFFERENTIATE THIS PRICE AND NOT HAVE A SINGLE PRICE
9 TO HMO'S AND OTHER PROVIDERS OF MEDICAL CARE.

10 CHAIRMAN CHIANG: THANK YOU.

11 MR. KLEIN: THANK YOU VERY MUCH.

12 MR. SIMPSON: JOHN SIMPSON FROM CONSUMER
13 WATCHDOG. FIRST OF ALL, I'D LIKE TO SIMPLY SAY THAT
14 I WAS A PART OF THE ONGOING DEVELOPMENT OF THE IP
15 POLICY REGULATIONS, AND I WOULD HAVE TO COMMEND THE
16 AGENCY IN THE WAY THAT THEY WENT THROUGH THAT AS
17 BEING A MODEL FOR THE WAY PUBLIC POLICY SHOULD BE
18 DEVELOPED. I DID NOT AND DO NOT AGREE COMPLETELY
19 WITH THE OUTCOMES OF SOME OF THAT POLICY. I DO
20 HAPPEN TO BELIEVE, FOR INSTANCE, IN THE CASE OF
21 UNREASONABLE PRICING, THE STATE ATTORNEY GENERAL
22 SHOULD BE ABLE TO INTERVENE. THAT'S NOT PROVIDED,
23 BUT WE'RE GOING TO CONTINUE TO WORK FOR THAT.

24 BUT TO THE SPECIFIC POINT OF 1565, I SEE
25 THIS AS CODIFYING WHAT WAS WORKED OUT IN A LONG,

BARRISTERS' REPORTING SERVICE

1 SOMETIMES GRUELING, BUT VERY GOOD REGULATORY
2 PROCESS. SO I SEE 1565 ESSENTIALLY AS CODIFYING
3 WHAT WAS ESTABLISHED. AND WHEN I HEAR FLEXIBILITY
4 AND THE NEED FOR IT IN THE FUTURE, I WORRY ABOUT THE
5 END RUNS THAT THE PHARMA INDUSTRY MAY PULL AROUND US.
6 SO I DO BELIEVE THAT THE CODIFICATION IS VERY
7 IMPORTANT.

8 AND THE OTHER THING I THINK IS VERY WORTH
9 NOTING IS THAT WHEN THIS CAME UP IN THE PAST, THERE
10 WAS NOT A GREAT ABILITY OR WILLINGNESS OR SOMETHING
11 ON THE PART OF CIRM TO WORK CONSISTENTLY WITH THE
12 LEGISLATURE AND TRY TO COME UP WITH APPROPRIATE
13 LANGUAGE. SO WHILE I'M NOT NECESSARILY GOING TO BE
14 COMPLETELY HAPPY WITH THE OUTCOME, I'M ENCOURAGED AT
15 WHAT I CONTINUE TO HEAR OF THE CHAIRMAN AND HIS
16 STAFF WORKING WITH THE SENATORS AND THEIR STAFF TO
17 DEVELOP CODIFICATION THAT MAKES SENSE. AND SO I
18 THINK THAT'S A GOOD THING, AND ALL INVOLVED SHOULD
19 BE COMMENDED FOR THAT.

20 AND I THINK SOMETIMES THAT HAPPENS
21 PRECISELY BECAUSE LEGISLATION IS BEING PROPOSED AND
22 BEING DISCUSSED AND BEING PART OF THE PUBLIC DEBATE.
23 SO WE SUPPORT 1565. WE SUPPORTED THE PROCESS IN THE
24 REGULATIONS, AND WE THINK THAT THIS ULTIMATELY IS
25 GOING TO END UP WITH SOMETHING THAT MIGHT NOT BE AS

BARRISTERS' REPORTING SERVICE

1 GOOD AS WE WOULD LIKE TO SEE, BUT WILL BE BETTER
2 THAN HAD WE NOT GONE THROUGH THE PROCESS. THANK
3 YOU.

4 CHAIRMAN CHIANG: THANK YOU.

5 MR. REED: DON REED, CALIFORNIANS FOR
6 CURES. MY SON, ROMAN REED, IS PARALYZED. HE IS IN
7 ONE OF THOSE ORPHAN DISEASE CONDITIONS THAT YOU
8 HEARD ABOUT. IT WOULD BE GREAT IF THE ICOC
9 MAINTAINED THE FLEXIBILITY SO THAT THEY COULD OFFER
10 A DIFFERENT PRICING. SUPPOSE GERON HAS TWO THINGS
11 THEY WANT TO WORK. ONE IS HEART DISEASE; ONE IS
12 SPINAL CORD INJURY. WE COULD SAY, ALL RIGHT. WE'RE
13 GOING TO LET YOU HAVE THE SECOND LEVEL SO YOU CAN
14 MAKE MORE MONEY OFF HEART DISEASE IF YOU WILL PUT
15 MONEY INTO SPINAL CORD INJURY. THIS IS THE KIND OF
16 FLEXIBILITY AND CREATIVE THINKING THAT'S BEEN THE
17 HALLMARK OF THE CALIFORNIA INSTITUTE FOR
18 REGENERATIVE MEDICINE.

19 MOST GOVERNMENT AGENCIES WHEN YOU CUT OFF
20 THEIR FUNDING, THEY JUST DIE. NOT CALIFORNIA
21 INSTITUTE OF REGENERATIVE MEDICINE. THEY WENT OUT
22 AND SAID TO THE PEOPLE, WE WANT YOU GUYS TO LOAN US
23 MONEY, AND MAYBE WE'LL PAY YOU BACK AND MAYBE WE
24 WON'T BE ABLE TO; BUT BECAUSE THEY BELIEVED IN WHAT
25 WAS TRYING TO BE DONE, THEY GAVE THE MONEY. AND IT

BARRISTERS' REPORTING SERVICE

1 CONTINUED. I SAY WE. THIS IS ME. THIS IS
2 CALIFORNIA. THIS IS MY THING. I LOVE THIS. THIS
3 IS THE MOST WONDERFUL THING IMAGINABLE.

4 I OBJECT TO THE EMBRYONIC STEM CELL
5 RESEARCH PREFERENCE WHICH CALIFORNIA STRONGLY VOTED
6 FOR BECAUSE IT WAS BEING SHOT DOWN AT THE FEDERAL
7 LEVEL. EVEN NOW NONEMBRYONIC STEM CELLS ARE BEING
8 FUNDED SEVEN TIMES AS MUCH BY THE FEDERAL AS ARE
9 EMBRYONIC. THE CALIFORNIA PROGRAM IS A BALANCING TO
10 THAT.

11 FINALLY, THE MOST IMPORTANT THING IS THAT
12 OTHER NATIONS NOW ARE LINING UP TO WORK WITH THE
13 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
14 BECAUSE THEY RECOGNIZE WHAT IS TOO EASILY MISSED.
15 THIS IS SOMETHING INCREDIBLE. CANADA JUST PUT UP A
16 100 MILLION BUCKS TO WORK STRICTLY WITH CALIFORNIA
17 INSTITUTE FOR REGENERATIVE MEDICINE BECAUSE THEY CAN
18 SEE WHAT IT IS. THIS IS SOMETHING WONDERFUL. IF
19 IT'S NOT BROKE, DON'T FIX IT.

20 MS. PARK: MR. CHAIRMAN, IF I MIGHT JUST
21 ADDRESS CHAIRMAN KLEIN'S LAST COMMENT. I DON'T
22 OBVIOUSLY WANT THIS TO BE A BACK AND FORTH BETWEEN
23 HE AND I, BUT I DO JUST WANT TO CLARIFY FOR THE
24 RECORD THAT WE DO DISAGREE WITH CHAIRMAN KLEIN'S
25 INTERPRETATION OF THE REGS AND THE BILL IN TERMS OF

BARRISTERS' REPORTING SERVICE

1 THE PRICING PROVISIONS AGAIN. AND THIS IS WHAT I
2 HOPE WE CAN WORK ON WITH PERHAPS SOME HELP FROM
3 STAFF AT THE DEPARTMENT OF HEALTHCARE SERVICES AS
4 WELL AS POSSIBLY PARTIES THAT CHAIRMAN KLEIN IS ALSO
5 SPEAKING WITH BECAUSE I DO NOT BELIEVE THAT THE
6 REGULATIONS OR THE PROVISIONS OF THE BILL PROHIBIT A
7 PRICE LOWER THAN LOWEST COMMERCIAL PRICE.

8 THERE WAS A QUESTION THAT CAME BY WAY OF
9 SUE NORTH ABOUT WHETHER ANY SORT OF CHARITY CARE OR
10 ANY SORT OF SPECIAL DISCOUNTS GIVEN TO INDIVIDUALS
11 WOULD HAVE ANY IMPACT ON BEST PRICE OR ON WHAT WAS
12 GIVEN TO COMMERCIAL PAYERS OR OTHER PAYERS. AND THE
13 ANSWER, WE BELIEVE, IS NO. IT HAS NO BEARING
14 BECAUSE PHARMACEUTICAL COMPANIES NOW ROUTINELY DO
15 CHARITY CARE AND DO OTHER TYPES OF DEEP DISCOUNTS
16 THAT ARE NOT FACTORED INTO ANY SORT OF BEST PRICE
17 SCENARIO OR OTHER PRICING SCENARIO.

18 SO THIS IS SOMETHING THAT WE HOPE THAT
19 WE'LL BE ABLE TO AT LEAST CLARIFY WHAT THE
20 INTERPRETATION IS BECAUSE THAT IS NOT OUR GOAL
21 CLEARLY IN THE BILL, AND I DON'T BELIEVE THAT THE
22 BILL ACTUALLY DOES THAT. THANK YOU.

23 CHAIRMAN CHIANG: THANK YOU. OTHER PUBLIC
24 COMMENTS? OKAY.

25 NEXT ITEM, ITEM 11, FORMAL ADOPTION OF

BARRISTERS' REPORTING SERVICE

1 CONFLICT OF INTEREST CODE PURSUANT TO FAIR POLITICAL
2 PRACTICES COMMISSION REGULATION, SECTION
3 18751(C)(3). AT OUR LAST MEETING THE COMMITTEE
4 VOTED TO ADOPT THE CONFLICT OF INTEREST PURSUANT TO
5 THE FPPC. OUR ATTORNEY SUBSEQUENTLY INFORMED US
6 THAT PRIOR TO OUR ADOPTION OF THE COMMITTEE -- PRIOR
7 TO OUR ADOPTION, THE COMMITTEE HADN'T NOTICED THE
8 OFFICE OF ADMINISTRATIVE LAW OF OUR INTENT TO COMPLY
9 WITH THE FPPC FILING REQUIREMENTS.

10 THIS WAS COMPLETED, SO AT THIS MEETING WE
11 CAN NOW FORMALLY ADOPT THE CONFLICT OF INTEREST
12 VOTE. IS THERE ANY DISCUSSION OF THIS ISSUE? MAY I
13 HAVE A MOTION?

14 MEMBER BRUNNER: SO MOVED.

15 MEMBER SADANA: SECOND.

16 CHAIRMAN CHIANG: WE HAVE A MOTION BY
17 BRUNNER, SECOND BY SADANA. WITHOUT OBJECTION,
18 MOTION PASSES.

19 NEXT ITEM IS 12, CONSIDERATION OF ITEMS
20 FOR THE NEXT DRAFT AGENDA. ARE THERE ANY ITEMS THAT
21 THE MEMBERS WANT TO RECOMMEND FOR OUR NEXT MEETING?
22 NO.

23 OKAY. ITEM NO. 13, PUBLIC COMMENT. DOES
24 ANYBODY WISH TO MAKE ANY ADDITIONAL COMMENTS?

25 MR. SIMPSON: JOHN SIMPSON FROM CONSUMER

BARRISTERS' REPORTING SERVICE

1 WATCHDOG. I JUST WANTED TO BRIEFLY SAY THAT I THINK
2 EVERYONE HERE UNDERSTANDS THE IMPORTANCE OF THIS
3 ENTERPRISE GOING FORWARD BEING DONE WITH THE UTMOST
4 OF TRANSPARENCY, AND THAT THAT BUILDS PUBLIC TRUST.
5 AND I JUST WANT TO THANK EVERYONE FOR THEIR ROLE IN
6 THAT, AND ALSO WANT TO THANK CIRM EXECUTIVES WHO ARE
7 HERE FOR THEIR ONGOING EFFORTS IN THAT REGARD TOO.
8 SOMETIMES IT'S NECESSARY TO HOLD PEOPLE'S FEET TO
9 THE FIRE TO MAKE SURE THAT THAT HAPPENS. I FIND
10 MYSELF SOMETIMES IN THAT ROLE.

11 I WOULD SAY PERHAPS OF LATE THAT'S BEEN
12 SOMEWHAT LESS NECESSARY THAN IT HAD BEEN IN THE
13 BEGINNING, AND THAT MAKES US ALL FEEL VERY GOOD.
14 THANK YOU.

15 CHAIRMAN CHIANG: THANK YOU, JOHN. ANY
16 OTHER COMMENTS?

17 ITEM 14, BOARD MEMBER TIME. ANY COMMENTS?
18 OKAY.

19 I'LL MAKE A STATEMENT. AT THE LAST
20 MEETING CONCERNS WERE EXPRESSED ABOUT THE THEN
21 RECENTLY PUBLICIZED REPORTS ABOUT POTENTIAL
22 VIOLATIONS OF STATE CONFLICT OF INTEREST RULES BY
23 DR. JOHN REED, AN APPOINTEE OF THE ICOC. AS CHAIR
24 OF THIS COMMITTEE, I MADE A REQUEST OF THE FPPC TO
25 INVESTIGATE. TO DATE WE HAVE NOT RECEIVED A

BARRISTERS' REPORTING SERVICE

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RESPONSE.

ITEM NO. 15, WE ARE ADJOURNED. THANK YOU
VERY MUCH, EVERYBODY, FOR YOUR PARTICIPATION.

(THE MEETING WAS CONCLUDED AT 03:27
P. M.)

BARRISTERS' REPORTING SERVICE

REPORTER' S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDING BEFORE THE CITIZENS FINANCIAL ACCOUNTABILITY AND OVERSIGHT COMMITTEE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

1600 PACIFIC HIGHWAY
ROOM 301
SAN DIEGO, CALIFORNIA
ON
JULY 7, 2008

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.



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